ASSESSMENT OF THE HEALTH RELATED QUALITY OF LIFE AMONG ADULTS WITH EPILEPSY LIVING IN KANIYAMBADI BLOCK OF VELLORE DISTRICT AND FACTORS ASSOCIATED WITH POOR QUALITY OF LIFE AMONG THEM

DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENT OF THE TAMIL NADU DR M.G.R MEDICAL UNIVERSITY, CHENNAI, FOR THE DEGREE OF MD BRANCH-XV (COMMUNITY MEDICINE) EXAMINATION TO BE HELD IN APRIL, 2017

CERTIFICATE

This is to certify that "Assessment of the health related quality of life among adults with epilepsy living in Kaniyambadi block of Vellore district and factors associated with poor quality of life among them" is a bona fide work of Dr Fernandes Dolorosa Eleuterio in partial fulfillment of the requirements for the MD Community Medicine examination (Branch – XV) of the Tamil Nadu Dr M.G.R. Medical University, Chennai, to be held in April, 2017

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DECLARATION

I hereby declare that the investigations that form the subject matter for the thesis entitled "ASSESSMENT OF THE HEALTH RELATED QUALITY OF LIFE AMONG ADULTS WITH EPILEPSY LIVING IN KANIYAMBADI BLOCK OF VELLORE DISTRICT AND FACTORS ASSOCIATED WITH POOR QUALITY OF LIFE AMONG THEM" was carried out by me during my term as a post graduate student in the Department of Community Health, Christian Medical College, Vellore. This thesis has not been submitted in part or full to any other university.

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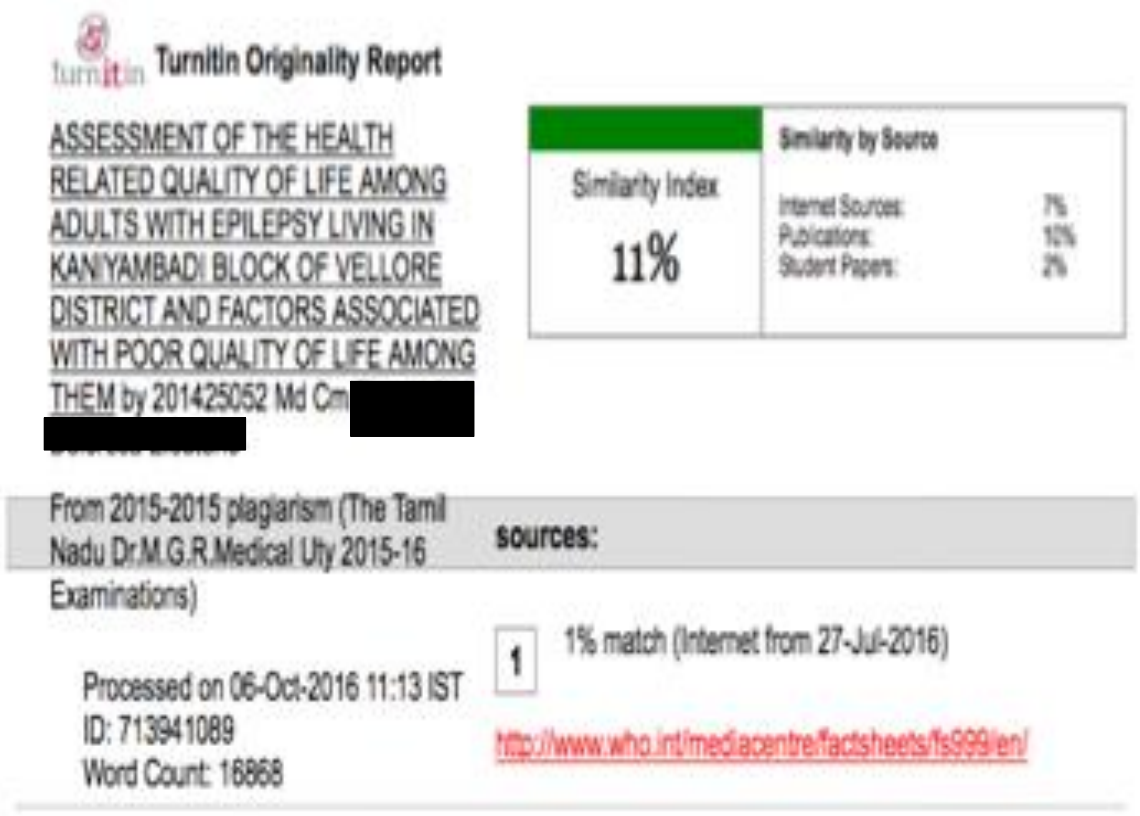

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Glossary of abbreviations

ADR	Adverse Drug Reaction
AED	Anti-Epileptic Drugs
CHAD	Community Health And Development program
CMC	Christian Medical College
DALY	Disability Adjusted Life Years
GAD-7	Generalized Anxiety Disorders-7
HA	Health Aide
HIS	Health Information System
HRQOL	Health Related Quality of life
ILAE	International League Against Epilepsy
IRB	Institutional Review Board
LAEP	Liverpool Adverse Effects Profile
PHC	Primary Health Center
PHN	Public Health Nurse
PHQ-9	Patient Health Questionnaire-9
PTCHW	Part Time Community Health Worker
PWE	Persons With Epilepsy
QOL	Quality Of Life
QOLIE-10	Quality Of Life In Epilepsy-10
QOLIE-31	Quality Of Life In Epilepsy-31
QOLIE-89	Quality Of Life In Epilepsy-89
SES	Socio-Economic Status
SSQ	Seizure Severity Questionnaire

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1 Introduction

Epilepsy also known as seizure disorder is a condition known and written about since a long time. Since archaic times, epilepsy was believed to be a curse of the Gods or possession by evil spirits and the individuals with epilepsy were shunned and ostracized. The treatment of epilepsy was the domain of priests and not physicians.(1)

In more recent times the treatment of epilepsy has moved from isolation in asylums to treatment at home and in the community with anti-epileptic medications. Similarly the treating physicians have changed from psychiatrists to neurologists, as the understanding of the condition has progressed.(2)

Our understanding of the causation of epilepsy has notably advanced and had been reflected in the revised classifications of the condition. However, there are still lacunae in the knowledge about the causal pathway of many of the disease processes which result in epilepsy.(3)

The International League Against Epilepsy (ILAE) has defined epilepsy as "a disease of the brain defined by any of the following conditions:

1. At least two unprovoked or reflex seizures occurring greater than twenty-four hours apart
2. One unprovoked or reflex seizure and a probability of further seizures similar to the general recurrence risk (at least 60%) after two unprovoked seizures, occurring over the next 10 years
3. Diagnosis of an epilepsy syndrome" (4)

The World Health Organization (WHO) has estimated that approximately 50 million people have epilepsy in the world, with 2.4 million new cases being diagnosed each year.(5)

In India, the prevalence of epilepsy has been estimated to be 5.35 per thousand population, with majority of the population living in rural areas.(6) The cost of treating these individuals was calculated to be Rs. 13,755 per patient per year.(7)

The chronic nature of the condition and the significant burden that it places on the individuals and their families leads to a deterioration in the quality of life in the individual.

The quality of life (QOL) is an important patient reported, indicator of health. It reflects the individuals opinion of his or her status and functionality in the family and community.(8)

The quality of life of people with epilepsy is known to be poor, as compared to normal individuals.(9) However, the causes for poorer quality of life among the patients with epilepsy is not clearly known.(10)

Given the large burden of individuals with epilepsy in India, and the estimated treatment gap of up to 70%, it is important to know, what is the quality of life of individuals with epilepsy and what are the possible associated risk factors among the individuals with epilepsy that can be modified.(6) Therefore, this study aims to primarily estimate the quality of life and secondarily, evaluate the risk factors for poor quality of life.

2 Justification

There is a considerable burden of epilepsy in India, with an estimated prevalence of 5.35 per thousand population, along with an estimated treatment gap of up to 70%.(6) There are very few studies which have evaluated the quality of life of patients with epilepsy in India, and most of them have been conducted in hospital settings. There is likely to be a difference in the individuals who come to hospital as compared to those who do not, and the optimal method to evaluate the quality of life of individuals would be to conduct community based studies. While using general instruments like the WHO quality of life survey instrument helps in comparing the quality of life across disease conditions, within epilepsy, use of disease specific scales gives a better understanding of the quality of life.(11)

The protective as well as risk factors for the poor quality of life if known, can help direct future research to formulate more effective strategies to help individuals and their families to cope with the disease thus, improving their quality of life and decrease the burden on individuals, their families and the community. Individuals who have poor quality of life can be offered more support in terms of counseling or changes in medication.

Knowledge of the risk factors for poor quality of life can lead to possible interventions that modify the risk factors and can improve the quality of life of the individuals. For individuals this can lead to better management of their disease condition and changes in the way epilepsy is managed and treated on a wider level.

3 Objectives

1. To assess the Health Related Quality of Life (HRQOL) among persons aged 18 years and above living with epilepsy residing in Kaniyambadi block, Vellore.
2. To identify the risk factors associated with poor HRQOL in persons living with epilepsy residing in Kaniyambadi block, Vellore.

4 Review of literature

4.1 History of epilepsy

Epilepsy is an ancient disease, known to humanity for a very long time and descriptions of epilepsy can be found in many ancient texts, with reference to it found in texts written in 4000 BC. An attack of epilepsy can be frightening, both for the sufferer and for the observers. Hence it is no surprise that, evil spirits has considered epilepsy a curse of the Gods, or a disease of possession. The supernatural causation theory has been associated with epilepsy for so long that people with epilepsy were stigmatized and excluded from the community. Epileptic persons were more likely to be taken to faith healer or religious head than to a physician.(2)

Causation of epilepsy was attributed to Gods and evil spirits, therefore the treatment also was focused towards appeasing the Gods or removing the evil spirits from the person.(1) Till the nineteenth century the cause of epilepsy was not localized. The causes of epilepsy were thought to be of physiological or genetic origins. Epilepsy was associated with both neurology and psychiatry, due to the association of psychiatric manifestations with epilepsy. Although in the seventeenth century epilepsy had been identified as a neurological condition, it was only in 1960 that the World Health Organization (WHO) classified epilepsy as a neurological condition and not a psychiatric condition.(1,2)

4.2 Definitions

Epilepsy is a long-term disturbance of the brain functioning, distinguished by recurrent seizures. Seizures are brief episodes of involuntary movement that may involve a part of the body (partial) or the entire body (generalized), and sometimes occur with loss of consciousness and bowel and bladder incontinence.(5)

Uncontrolled electrical discharges in a group of neurons results into seizure episodes. Any site in the brain can be a source of such discharges. Seizures can vary from generalized full body involvement to brief lapses in attention and or repetitive activity or muscle jerks. This can also vary in frequency from several episodes in a day to less than one per year. A single episode of seizure does not mean epilepsy, as upto 10% of people worldwide have experienced at least one episode of seizure during their lifetime. For a diagnosis of epilepsy to be established at least 2 or more unprovoked seizures need to be present in an individual. Epilepsy is also known as ‘seizure disorder’ especially in setting where establishing cause of seizures is difficult or not easily possible.(4,12)

Seizures are classified based into three broad families as generalized, focal or unknown. Generalized seizures are arising within and rapidly engaging bilaterally distributed networks in both hemispheres of the brain. Focal seizures start from neuronal networks restricted to one hemisphere, but can also develop into generalized seizures. Each of these broad categories is further divided into subcategories based on type of clinical manifestation of seizure. For example

generalized seizures are divided into tonic-clonic, tonic, clonic, atonic, absence and myoclonic type of seizures.(4)

An alternative classification is based on electro-clinical syndromes, which are arranged by typical age at onset into neonatal, infancy, childhood, adolescence-adult and familial epilepsy syndromes, however these do not represent etiology.(4)

The International League Against Epilepsy (ILAE) provides an operational definition for epilepsy as a disease of the brain defined by "any of the following conditions(13):

a) At least two unprovoked or reflex seizures occurring greater than twenty four hours apart
b) One unprovoked or reflex seizure and a probability of further seizures similar to the general recurrence risk (at least 60%) after two unprovoked seizures, occurring over the next 10 years
c) Diagnosis of an epilepsy syndrome"

Individuals who have remained seizure free for a period of ten years, with last five years without medications or those who had an age dependent epilepsy syndrome but are now past the applicable age are considered to be cases of resolved epilepsy.(13)

According to the ILAE classification epilepsy is currently classified into generalised, focal and unknown depending on type of seizure pattern and syndromic classification based on age of onset into neonatal period, infancy, childhood, adolescence adult and familial epilepsy syndromes. Each category is

then further divided based either on seizure pattern or on known cause for syndromic classification.(14)

4.3 Etiology

Epilepsy is not a single disease or disorder but a family of different disease processes. From supernatural causation, the causation of epilepsy has moved to predisposing factors and precipitating factors after publication of case series by medical specialists like Gowers in 1881 and Turner in 1907. Then between 1900 and 1950s the causation of epilepsy spilt into two main divisions: inherited causes and structural causes of epilepsy. The newer modalities of imaging, biochemical and genetic research in the latter part of the twentieth century have led to the current concepts of causation of epilepsy.(3)

There is still a great deal of confusion in the etiological basis of epilepsy. The commonest type of epilepsy is idiopathic with no identified cause. The known causes of epilepsy include genetic factors, trauma, infections like neurocysticercosis, perinatal trauma, stroke and brain tumours.(5)

Seizure disorder or epilepsy can be due to identified causes or can be idiopathic. When an identified cause is present, epilepsy is sometimes called secondary epilepsy. Some of the common causes include perinatal hypoxia, congenital anomalies or brain malformations, severe head injuries, stroke, infections such as meningitis, encephalitis, neurocysticercosis, genetic syndromes like channelopathies, Facilitated Glucose Transporter type 1(GLUT-1) deficiencies, and brain tumors.(12)

Etiology of epilepsy can be due to known and unknown causes. Up to 40% of the adult onset epilepsy cases are cryptogenic. The assignment of cause for epilepsy is also dependent on the level of investigations carried out, for example Magnetic Resonance Imaging (MRI) or genetic tests for familial epilepsies. The etiologies are also categorized into idiopathic, symptomatic epilepsy of simple or complex genetic causation, acquired epilepsy in which cerebrovascular accidents, tumors, trauma, infection fit in, provoked epilepsy which include menstrual, drug induced epilepsy, hot water epilepsy and cryptogenic epilepsy where the cause is still unknown.(15)

Epilepsy is generally multifactorial in causation. There are both genetic and acquired causes or sometimes pre-disposing and provoking causes making allocations to a particular cause discretionary.

Some experts like Hughlings Jackson and Shorvan believe that ascribing etiology by mechanism is more preferable than by underlying cause, as the final pathways for seizures is the same. However until knowledge about the causation of epilepsy improves, this remains a utopian concept.(15) A major problem in ascribing causes to epilepsy is the confusion in whether epilepsy is a disease or a symptom of a disease. In earlier classifications, epilepsy was considered a disease if there was no obvious cause found and a symptom if there was an obvious cause. At the end of all causal pathways, whether anatomical, physiological, predispose individual to the uncontrolled electrical activity that leads to seizures.(15)

4.4 Burden of epilepsy in the world

According to the WHO, approximately fifty million people currently live with epilepsy in the world. Active epilepsy as defined by continuing seizures with need for treatment is estimated to be 4 to 10 per thousand population. In lower and middle income countries the proportion is said to be higher between 7 to 14 per thousand population.(12)

Approximately 2.4 million people are diagnosed with epilepsy each year, across the world. The incidence varies from thirty to fifty per 100,000 people in the general population in high-income countries but in low and mid-income countries, the estimate is two times higher. This is most probably due to the higher risks of endemic conditions like malaria and neurocysticercosis, higher incidence of birth related problems, road traffic injuries and availability and accessibility of medical care. Almost 80% of people with epilepsy live in low to middle income countries.(12)

One of the measures of disease burden in the world is by calculating the Disability Adjusted Life Years or DALY. The disability adjusted life years is a combination of the years of life lost due to a condition as well as the morbidity or disability caused by the condition.(16)

According to the Global Burden of disease survey 2000, the burden due to epilepsy was around 0.5 % of the total burden of disease in the world and around fifty million people were affected by epilepsy.(17) Epilepsy accounts for 0.75% of the global burden of disease, and in 2012 was the cause of 20.6 million DALYs lost.(12)

The global burden of disease study (2010) looked at neurological, mental and substance use disorders. The study found that 10.4% of the global DALYs were contributed by mental, neurological and substance use disorders. Most of the DALYs for epilepsy were contributed by males than females.(18)

4.5 Burden of epilepsy in India

A meta-analysis of studies published in India on the prevalence of epilepsy including 20 studies, revealed a crude prevalence rate of 5.35 per thousand population. The adjusted prevalence was 5.33 per thousand population. Prevalence among urban population was 5.11 per thousand population, rural was 5.47 (4.04 - 6.9); men 5.88 (3.89 - 7.87); and women 5.51 (3.49 - 7.53). This analysis also found that the age specific prevalence was higher in younger age groups as compared to older people. The treatment gap for epilepsy was close to 70% in rural areas. It has been estimated that the total number of cases in India would be 5.5 million, and as majority of the population is still living in rural areas with a 70% treatment gap, this would mean a majority of the epileptics would not be getting any treatment.(6)

A group of researchers from Kolkata undertook a population based prospective study to look for both the prevalence as well as the burden of epilepsy in the community. They found that DALYs lost due to epilepsy were more in men (1183.04) than women (463.81). The overall burden of disease was 846.96 per 100,000.(19)

Another study reported the disease burden estimates to be around 10 million people in India. The prevalence rates from studies in India range from 5.59 to

10 per thousand population, with prevalence reportedly higher in males and in rural areas.(20) The economic cost of epilepsy was calculated in 2001 to be Rs. 68.75 billion, in a study conducted across six states in India in epilepsy centres attached to university hospitals.(7)

In Vellore district of Tamilnadu, community surveys have estimated the prevalence of active epilepsy to be 3.83 per thousand with prevalence in urban clusters double than that of rural areas. The cause of epilepsy was diagnosed to be neurocysticercosis in 55 out of 194 cases of active epilepsy, which was 33% of the cases. The prevalence of neurocysticercosis linked epilepsy was 1.28 in urban versus 1.02 per thousand in rural areas.(21)

4.6 Complications of epilepsy

Epilepsy and injuries: A review published in 2006 summarized the studies published on injuries in epilepsy. Most studies were retrospective and compared the relative risk of vehicular accidents (Rate ratio 1.33), drowning (RR 13.8), burns (3.7% - 15.9% of adults), fractures (2.39 increased risk), head injuries (OR 2.6), and soft tissue injuries (up to 74% of all injuries). The recommendations for prevention of injuries included supervision, use of harnesses and restriction of activities like scuba diving and regulation of the temperature of hot water.(22)

Epilepsy and pregnancy: A review published in 2015 looked at women with epilepsy, during and after their pregnancy and described the outcomes of the pregnancy. Women who were on Lamotrigine (58% were seizure free) rather than Valproate (75% were seizure free) had more episodes of seizures, but

overall 66% were seizure free during pregnancy. Another study found that women with epilepsy were more likely to have preterm births. It was also reported that women with pre-pregnancy seizures were more likely to have seizures during pregnancy. During seizures, there are effects on the fetus like likelihood of preterm delivery, reduced birth weight, as well as cognitive effects on the child. In conditions like status epilepticus, the possibility of fetal malformations and death of mother and child are high. Even otherwise women with epilepsy have a 10 times higher risk of dying during pregnancy compared to women without epilepsy.(23)

Epilepsy and sudden death

Epilepsy is associated with sudden unexpected death, and it is major cause of death in those persons who do not respond to anti-epileptic medications. It is reported to cause upto 17% of the deaths in epilepsy. The mechanisms that cause this condition are not clearly understood, but is possibly due to cardiac abnormalities and autonomic dysfunction. The preventive measures recommended include better control of seizures, and evaluation for any possible cardiovascular problems.(24)

4.7 Quality of life

Quality of life is a concept that has different philosophical, political and health-related definitions. In common terms it refers to the physical, social or emotional or spiritual wellbeing of individuals. Health related quality of life refers to the components of physical, functional, social and emotional wellbeing of an individual. It is usually a patient reported outcome measured

by structured questionnaires or interviews. It is one of the few outcome measures where well-being is considered from the patient's point of view.(8)

The WHO defines Quality Of Life (QOL) as "Individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns". QOL is understood to be a wide-ranging concept, in which factors like physical health, psychological health, level of independence, social relationships, personal beliefs and relationships with relevant features of the environment all play a role.(25)

The concept of Health Related Quality Of Life (HRQOL) includes all those factors which influence health either positively or negatively. It can be categorised into levels such as individual level factors like health risks and conditions, functional status, social status and socio-economic status. On a community level it can include policies, practices, resources and conditions which effect quality of life.(26)

There are various ways in which disease burden can be measured using morbidity and mortality indicators but it is more difficult to measure well-being or health. Therefore, the WHO developed tools such as the World Health Organisation Quality of Life (WHOQOL) tools to be able to measure the health and wellbeing of individuals. These tools were developed and validated to be relevant across cultures and countries. The WHOQOL was developed as 100 questions tools from which a brief 26 item assessment was developed called WHOQOL-BREF. The domains included in these scales are physical health,

psychological wellbeing, level of independence, social relationships, environment and spirituality/religion/personal beliefs.(25)

Health related quality of life is measured through tools such as WHO HRQOL questionnaire both full and brief versions, and Short Form 36 (SF-36), which are not disease specific, and HRQOL scales for specific disease conditions like epilepsy for example, Quality of Life in Epilepsy Inventory-89 (QOLIE-89), Quality of Life in Epilepsy Inventory-31 (QOLIE-31), Quality Of Life In Epilepsy (QOLIE-10) and Washington Psychosocial Seizure Inventory (WPSI) which are epilepsy specific scales.(26)

For epilepsy, disease specific scales have been developed by researchers because of the felt needs to have a cross-culturally acceptable and comparable scale to assess quality of life. Because of the chronic nature of epilepsy, just the seizure frequency and adverse effects of medications was not sufficient to assess the impact of both disease and to compare the relative merits of various modalities of treatment. To develop this tool, researchers first developed and validated a 89 item questionnaire which was later shortened to a 31 item inventory called Quality Of Life In Epilepsy-31 or QOLIE-31. This inventory was then translated into various languages and validated. The 10 item inventory or QOLIE-10 originated from QOLIE-31.(27)

A review that looked at quality of life scales used in epilepsy summarised the general and disease specific scales used in various studies including scales that assessed the effect on seizure severity on the life of the individual.(10)

4.8 Quality of life in people with epilepsy

In a study to assess the effects of seizure severity and freedom from seizures on HRQOL of people with epilepsy in Sub-Saharan Africa, QOLIE-31 was administered to 93 adults with epilepsy and 102 age and sex matched controls. A three item perceived stigma scale was administered. There was moderate negative correlation between seizure severity and mean total HRQOL score as well as scores on the subscales of Seizure Worry ($p < 0.001$), Overall Quality of Life ($p < 0.001$), and Social Function ($p = 0.001$). Overall, the healthy control subjects had a higher mean HRQOL score compared with the PWE put together (71.0 ± 11.1 vs. 64.2 ± 13.6, $p = 0.001$). However, there was no difference in the mean HRQOL score between the seizure-free individuals and the healthy controls ($p = 0.270$). Seizure severity was associated with HRQOL independent of perceived stigma on a multiple regression analysis.(28)

A study from Tunisia compared the QOL among people with epilepsy to those without epilepsy found that individuals with epilepsy had poorer quality of life. The factors modifying the effect of the disease included age of the individual and age at onset of disease.(29)

A study from Iran that compared the quality of life between people with epilepsy and without epilepsy using Short Form Health Survey (SF-36), found that the quality of life was worse in all domains of the quality of life scale, and this was statistically significant.(9)

4.9 Factors affecting quality of life in people living with seizure disorder:

4.9.1 Socio economic and demographic factors

Gender

A longitudinal study of sense of coherence and quality of life among people with epilepsy found that over a 10-year period there was no difference in quality of life among men and women. However the sense of coherence decreased over the 10-year period.(30)

Marital status

Two hundred and fifty-two people with epilepsy were evaluated using the QOLIE-31 scale. Single people had more abnormalities in neurological examination and early seizure onset. Married and divorced people had more psychiatric comorbidity and longer disease duration. Psychiatric comorbidity was significantly associated with poor quality of life score. The marital status of people with epilepsy had negative associated with clinical aspects of epilepsy.(31)

Occupational status

A Polish study which looked at the occupations of people with epilepsy included 197 patients, found that 47% of respondents had difficulty finding a job and 77.2% said that having a seizure at work had affected their jobs. The level of education had a positive association with working status. However there was no significant co-relation between employment status and duration, number and type of seizures.(32)

Education and literacy

A study looking at 172 patients with epilepsy in Bhutan, using QOLIE-31, found that the mean score was 48.89 (SD 17.7). The individuals who were younger, less educated and had higher levels of stigma had poorer quality of life scores.(33)

Researchers in Taiwan conducted a cross-sectional study among 260 patients with epilepsy using the QOLIE-31 questionnaire. The factors like presence of anxiety, depression, adverse effects of medications, absence of social support, higher seizure frequency, male gender and household income of 40,000 to 100,000 were significantly associated with the quality of life and contributed to 58.2% of the variance in the score.(34)

5.9.2 Co-morbid conditions

Somatic Comorbidities

Somatic comorbidities, describes the presence of two or more conditions simultaneous in an individual. With epilepsy, others conditions can co-exist due to causal, resultant or shared risk factor association. The commonest co-morbid conditions found with epilepsy include cerebrovascular disease and neurodegenerative conditions especially in individuals older than 60 years of age. Other conditions like intracranial tumors, migraine and sleep apnea, decrease the control over epilepsy. As the number of co-morbid conditions increases it leads to poorer quality of life, increased health care utilization, costs and mortality for the individual.(35)

A study looking for co-morbidities among people with epilepsy found that among 280 respondents, 83.2% reported some kind of headache and even inter-ictal headaches were associated with poorer quality of life.(36)

A study comparing people with psychogenic non-epileptic seizures with people with epileptic seizures found poorer quality of life in the former group. Somatization and alexithymia was associated with poorer quality of life.(37)

In Nigeria, energy was significantly lower among patients with comorbidities, and patients with multiple comorbidities had worse quality of life than those with single comorbidity.(38)

Depression

A systematic review published in 2013 included studies, which looked for an association between depression and epilepsy and included 14 studies. The overall pooled prevalence was 23.1% (95% CI 19.8% – 27.0%) with an odds ratio of 2.77 for active depression among persons with epilepsy. The lifetime risk of depression was calculated to be 2.20 (95% CI 1.07 – 4.51), with a prevalence of 13.0% (95% CI 5.1% – 33.1%).(39)

A study looking at illness perception to help explain the link between depression and quality of life examined 70 patients with epilepsy from a hospital in New York. The association between depression and quality of life was significantly mediated by negative illness perception.(40) A study in a cohort of Spanish patients with drug resistant epilepsy in comparison with controlled focal epilepsy using QOLIE-31 found that the rate of depressive symptoms were 60% in drug resistant epilepsy and 30% in controlled focal

epilepsy. Depressive symptoms and not seizure frequency were associated with poorer quality of life scores.(41)

A German study, which looked at differences in the quality of life between men and women and the prevalence of anxiety and depression in people with epilepsy, found that among 302 participants with epilepsy, the gender difference was most significant for depressive symptoms among women. The factors most associated with poor quality of life were adverse effects of medications and seizure worry.(42)

Studies which looked at depression and epilepsy in Montenegro, through a pharmacy claims database found that, the type of seizure, number of medications, medication adherence, anxiety and depression all affected quality of life.(43) A study from a cohort of 250 Canadian patients who were a part of the neurological diseases and depression study found that freedom from seizures for one year, the total number of medications and their side effects the presence of anxiety and depression and seizures related disability were associated with higher self-reported severity.(44)

Myers et al. in a study in the US found that Spanish-speaking immigrants had higher depression scores and more seizure worry compared with US born Hispanics. Non-Hispanics had better access to health coverage and were receiving more treatment for depression and more anti-epileptic medication than Hispanics.(45)

Anxiety and Epilepsy

A Korean study which looked at Liverpool adverse effects profile, Beck depression inventory, and Beck anxiety inventory, among 453 patients found that the anxiety score and the treatment duration had a significant association with poorer LAEP score.(46)

4.9.3 Stigma

A study which looked at factors associated with increased felt stigma found that poor quality of life at a younger age, group being single and lower literacy were associated with high degree of perceived stigma.(47)

An online study, conducted by Canadian researchers with 101 individuals with epilepsy found that social anxiety was more common with people with epilepsy and was associated with higher perceived seizure severity and stigma.(48)

A cross-country comparison study among European countries which looked at epilepsy associated stigma, overall health system performance, health expenditure and quality of life index found no relation between perceived discrimination, quality of health care and outlay on health care with quality of life.(49)

Verma et al. in a study among 80 people with epilepsy being treated at All India Institute of Medical Sciences (AIIMS) hospital Delhi India found that people who had relatives who expressed emotions regarding epilepsy had higher stigma and more depression.(50)

In a study in India to look at the impact of stigma associated with epilepsy on the quality of life of 208 people with epilepsy, using Indian Disability

Evaluation Assessment Scale (IDEAS) to measure disability, the Dysfunctional Analysis Questionnaire (DAQ) to measure QOL, and the Stigma Scale for Epilepsy (SSE) to assess stigma, found that stigma (SSE) was highly significantly related with QOL (DAQ) (0.019) and disability due to stigmatized epilepsy (IDEAS) (p = 0.011).(51)

4.9.4 Family functioning

A multi-Centre cross sectional study conducted in Korea on 391 adults with epilepsy and their caregivers found that care giver depression was significantly associated with depression in patients with epilepsy. Caregiver's perception of burden and the level of family function are associated with patient depression through caregiver depression.(52)

A case control study comparing 42 people with epilepsy to 42 people without epilepsy in China, found that support within the family predicted family cohesion and marriage quality. There were high levels of anxiety, depression, dissatisfaction with family functioning and marital life and poorer social support in people with epilepsy.(53)

Sleep disturbances

Prolonged sleep deprivation can provoke seizures in epilepsy. A sleep diary method was used to find relationship between total sleep time 24 and 72 hours before seizure occurrence and seizure occurrence. The study found that small degrees of sleep loss were not associated with increased seizure frequency. However, daytime sleepiness, fatigue and insomnia were common in people with epilepsy.(54)

A UK based survey which looked at anxiety and sleep problems from a mailed questionnaire, along with internet survey among patient with epilepsy and age and gender matched controls found that poorer general health, seizure worry, self-reported medication side effects were associated with higher anxiety and sleep problems. Good social support was the key factor for lower anxiety score. Sleep quality did not always predict quality of life. But trait anxiety was significant in overall quality of life.(55)

A study conducted among 150 adults from South Korea, with epilepsy to determine whether sleep hygiene is related to quality of life and mood using QOLIE-10, sleep hygiene index, hospital anxiety and depression scale, sleep problem index two and Epworth sleepiness scale found that more than 15% of the participants had inadequate sleep hygiene behavior. Quality of life, anxiety and depression symptoms were significantly associated with sleep hygiene scores.(56)

Hospital based studies indicate that up to 22% of non-refractory epilepsy group and 45% of the group with refractory epilepsy ($p < 0.0001$) suffered from some sleep disorder and patients with refractory epilepsy had a poorer quality of life ($p < 0.001$) as measured with the quality of life questionnaire QOLIE-10. A positive significant correlation was observed between quality of life and quality of sleep, in both cases of chronic insomnia ($r = 0.65$; $p < 0.0001$) and excessive daytime sleepiness ($r = 0.43$; $p < 0.0001$).(57)

A Korean study, assessed 702 individuals with epilepsy, who were utilizing outpatient clinics in secondary and tertiary level hospitals, using Korean

versions of Neurological Disorders Depression Inventory for Epilepsy (K-NDDI-E), the Generalized Anxiety Disorder-7 (GAD-7), the Quality of Life in Epilepsy-10 (QOLIE-10), and the Korean version of Liverpool Adverse Event Profile (K-LAEP). Household income, depression, anxiety, K-LAEP scores and seizure control, were all related to QOL and explained 68% of the variance in it. They concluded that anxiety did not have a direct effect on QOL; it had only indirect effect through the adverse effects of AEDs.(11)

Presence of co-morbidities like Sleep disturbance was associated with poor quality of life. A strong association between depression and anxiety and poor QOL scores were noted in multiple studies. Somatic co-morbidities were also associated with low QOL.

4.9.5 Seizure related factors

Use of anti-epileptic medication

A randomized multi-centric un-blinded clinical trial compared standard and new anti-epileptic medications over a two-year time period found that there was no significant effect of choice of medication on quality of life. The presence of continued seizures, adverse events and failure of the initial treatment resulted in poorer overall quality of life scores.(58)

Online groups of epilepsy patients have also been studied for reported quality of life. One group of researchers looked at 3,073 patients who participated in the study. The study tools included QOLIE-31, and found that problems concentrating, memory issues, depression, adverse effects, occurrence of

GTCS and seizures in last one year, were all associated with poor quality of life scores.(59)

Seizure freedom

A study that looked at seizure freedom and its effects on quality of life, among Korean patients found that recurrent seizures had a significant effect on quality of life scores, small effects on cognitive scores and no effects on psychological symptoms over one year in patients of partial epilepsy.(60)

Seizure frequency

A study from the United States of America, looking at the effect of seizure frequency on the preference based quality of life in 182 adult patients found that, irrespective of seizure frequency, only patients who had been seizure-free for >1 year had significantly higher preference-based HRQOL ($p < 0.0001$) than those who experienced any recurrent seizure. Among patients with recurrent seizures, preference-based HRQOL and seizure frequency were not monotonically, linearly related. For patients with similar seizure frequency, preference-based HRQOL varied widely. Monte Carlo simulation found that seizure frequency was a poor predictor of preference-based HRQOL about one third of the time. The presence of depressive symptoms was independently linked to preference-based HRQOL measures, explaining 33.5% of the variation in scores between patients.(61) In an Italian study aiming to compare the effects of perceived and assessed cognitive functions on quality of life in patients with epilepsy, the results were that cognitive functions, disease duration, seizure frequency and schooling determined the QOL score.(62) A

study in Belgrade, Serbia, found that the mean QOLIE-31 score of 203 patients who completed the questionnaires were 70.64±17.74. Socio-demographic factors (age, sex, education, and employment) did not significantly predict QOLIE-31 score. The important determinants of quality of life were seizure severity, aetiology of epilepsy, depression, anxiety and cognitive effects of antiepileptic drugs.(63) A study among 175 randomly selected persons with epilepsy from Ugandan national referral hospitals in 2011 used a HRQOL constructed using QOLIE-31 and Hospital Anxiety and Depression Scale (HADS) questionnaires. They found that about 54% of the respondents were male, and 62% had been on AEDs for a minimum of a year. On a scale of 0 to 100 the overall HRQOL mean score was 58 (SD = 13) on a scale of 0-100. The average scores of different domains ranged from 41 (physical) to 65 (psychological). A minimum of 75% of the sub scales had good adequacy and internal consistency. The biggest fluctuations in the overall HRQOL were explained by social and mental functioning; each accounting for about 30% of the difference in the HRQOL, but seizure control features explained a little (6%) variation. Factors associated with better QOL were being married of the female gender and having some formal education. Factors negatively associated with HRQOL were poly-therapy ($t = -1.16$, $p = 0.01$) and frequency of seizures ($t = -4.53$, $p < 0.001$). Duration of AEDs was not a significant predictor of HRQOL. They concluded that the HRQOL for epilepsy patients on AEDs was very low, and predicted by social factors (marital status, education) and drug side effects, frequency of seizure, and type of therapy.(64)

A study from Jaipur, India to assess the effects of clinical variables and quality of life among patients with epilepsy found that, only seizure frequency significantly correlated with seizure worry ($p = 0.002$), emotional well-being ($p = 0.026$) and social functions ($p = 0.013$) subscales of QOLIE-31 and concluded that seizure frequency and depression were the most important predictors of quality of life scores.(65) A cross sectional study, from Nagpur Maharashtra, evaluating the quality of life of people with epilepsy, in a teaching hospital and using QOLIE-31, studied 60 people. The individuals who were on single drug therapy had better score than those on multiple drugs.(66) QOLIE-89 was used to evaluate 60 individuals with epilepsy from Belgaum, India. Females, older individuals, married people, those having simple partial seizures, increasing duration of disease, and those who had their last seizure in the last 10 months had lower scores.(67)

There were 2 studies conducted in Bangalore both at tertiary care hospitals, using QOLIE-10, one study interviewed 451 patients with a mean score of 64.1 (SD 15.97). Univariate analyses showed that, factors such as lower monthly income, presence of focal epilepsy, higher seizure frequency, antiepileptic drug (AED) poly-therapy, conventional AEDs and frequent adverse drug reactions (ADRs) had significant negative influence on various domains of QOLIE-10 questionnaire. Multiple regression analysis showed seizure frequency as a significant predictor of most QOL domains and overall score, while ADRs as a significant predictor of all the domains. Seizure type was a predictive factor for domains like emotional well-being and overall score.(68) Similarly, another

study from Bangalore, found the presence of adverse events, increased number of medications and seizure frequency led to a worse quality of life.(69) A tertiary level centre in Kerala, catering to patients referred from smaller hospitals with 800-900 patients registered each year. Researchers looked at patients with age greater than 16 years with a QOLIE-31 based quality of life assessment. The study enrolled 112 patients with epilepsy and found multiple drug use and frequency of seizure (one or more seizures in a month) were associated with lower quality of life.(70)

There were 2 studies conducted in Vellore, one in a secondary care hospital and one community based study, both using WHOQOL-BREF. The hospital-based study found that the mean QOL score was 51.49 (SD 12.3) and being more than 30 years old, female or married was associated with poor quality of life scores.(71) While in the community-based study, the mean QOL score was 61.49 (SD 12.56) and being older, currently single or unemployed, not having completed primary school, having depression, anxiety and seizures in the past one year were all related to poor QOL scores.(72)

Most studies globally and from India found that as age increased the QOL scores decreased.(71,72) Being female, single separated or divorced, having lower education, and having lower economic status was also associated with poor QOL scores.(31,42,71,72) However one study from Serbia found that age, sex, education and employment made no difference to the QOL.(63)

Epilepsy related factors, disease related factors like poor control, severity, younger age at onset, high frequency of seizures, type of seizure were

associated with poor scores, while duration of disease was not related to poor QOL. Adverse events caused by anti-epileptic medications were also associated with low QOL scores.(11,34,58,69,73,74) Use of multiple anti-epileptic medications was found to be associated with poor QOL scores in some studies.(66,68–70)

5 Methodology

5.1 Study Setting

This study was conducted in Kaniyambadi block of Vellore district in northern Tamil Nadu.

The department of community medicine, Christian Medical College (CMC), has been working in Kaniyambadi Block of Vellore district for more than three decades. It provides community and hospital based health care services to around 1,16,000 population residing in 82 villages in the block. The Community Heath and Development (CHAD) program run by the department focuses on primary and secondary level of care and services emphasize on maternal, child and chronic diseases management. The services also include preventive and health promotive care through screening programs for non-communicable diseases (NCD) like cervical and breast cancers and NCD risk factors.

An important component of the CHAD program offered by the department is the mobile health clinic, where health care is provided at the doorstep of the community especially for the individuals with chronic diseases and antenatal mothers. This makes health care accessible to individuals both geographically as well as financially. The peripheral services are provided through a network of health care staff.

Grass root level volunteers are the Part Time Community Health Workers (PTCHWs), who are members of the local communities, usually married older

women, who volunteer their time in order to help serve their communities. They each serve a population of around 1,500 individuals and keep the Health Aides (HA) informed about vital events in their villages that includes births, marriages, pregnancies, illnesses and deaths in the community. The HA are full time staff of the community health department, each responsible for 5000 population and help maintain and update the Health Information System (HIS) maintained by the department. Public Health Nurses (PHN) and doctors supervise the health aides. Each PHN is responsible for a population of 20,000 individuals, and each area doctor is responsible for 40,000 individuals.

The nurses are involved in following up the homebound sick individuals, antenatal and postnatal mothers, and the sick children in the community.

Community health physicians at the Community Medicine Department supervise this entire system. The department maintains a computerized and regularly updated database of all residents of Kaniyambadi block. The population level census is conducted every 10 years, while vital events data and chronic diseases list is collected by the health aides, and entered into the HIS database on a monthly basis. The data entry managers verify the information thus collected.

The health care services available in the block include the services provided by CMC through outreach services, the 120 bedded secondary care hospital (CHAD) located at Bagayam. The government health services are provided through four Primary Health Centers (PHCs) and a tertiary level government medical college hospital.

5.2 Study population

The participants in the study were individuals who were identified as having seizure disorder or epilepsy, in the HIS records of the department. As mentioned above, the chronic disease lists and vital events are updated every month by the respective health aides, and entered after verification into the database.

All the individuals on the list were contacted, and eligible subjects available during home visits by the study investigator were included in the study.

5.3 Study design

The study design was a cross-sectional, population based study.

5.4 Institutional Review Board (IRB) and ethics committee approval

The Institutional Review Board of Christian Medical College, Vellore, evaluated the study proposal and, gave ethical clearance to conduct the study (ref. IRB Min. No. 9609 dated 1/9/2015).

5.5 Study Duration

Data collection was conducted from March 2016 to August 2016. The study participants were approached early in the mornings and late evenings on the weekdays and through out the day on weekends.

5.6 Inclusion criteria:

- Individuals who were identified as having epilepsy or seizure disorder from records (HIS) maintained by the community health department and by health aides.

- Individuals aged 18 years and above and permanent residents of the block (resided for at least six months).

5.7 Exclusion criteria:

- Pregnant women.
- Individuals who were temporary residents of Kaniyambadi block.
- Individuals who were unable to understand or answer the questions because of autism or psychiatric illness.

5.8 Sample size calculation:

Sample size was calculated using the formula

$$n = \left(\frac{(Z_{\alpha/2})(\sigma)}{E}\right)^2$$

Where,

N is the calculated sample size

$Z_{\alpha/2}$ is the critical standard score for two tailed distribution = 1.96 = 2

σ is the standard deviation obtained from previous study = 12.3 (71)

E is the margin of allowable error = 2

Therefore n= 4*12.3*12.3/4 =145

Providing for a 10% non-responder rate, the final sample size was estimated to be 160 individuals with epilepsy.

5.9 Informed consent

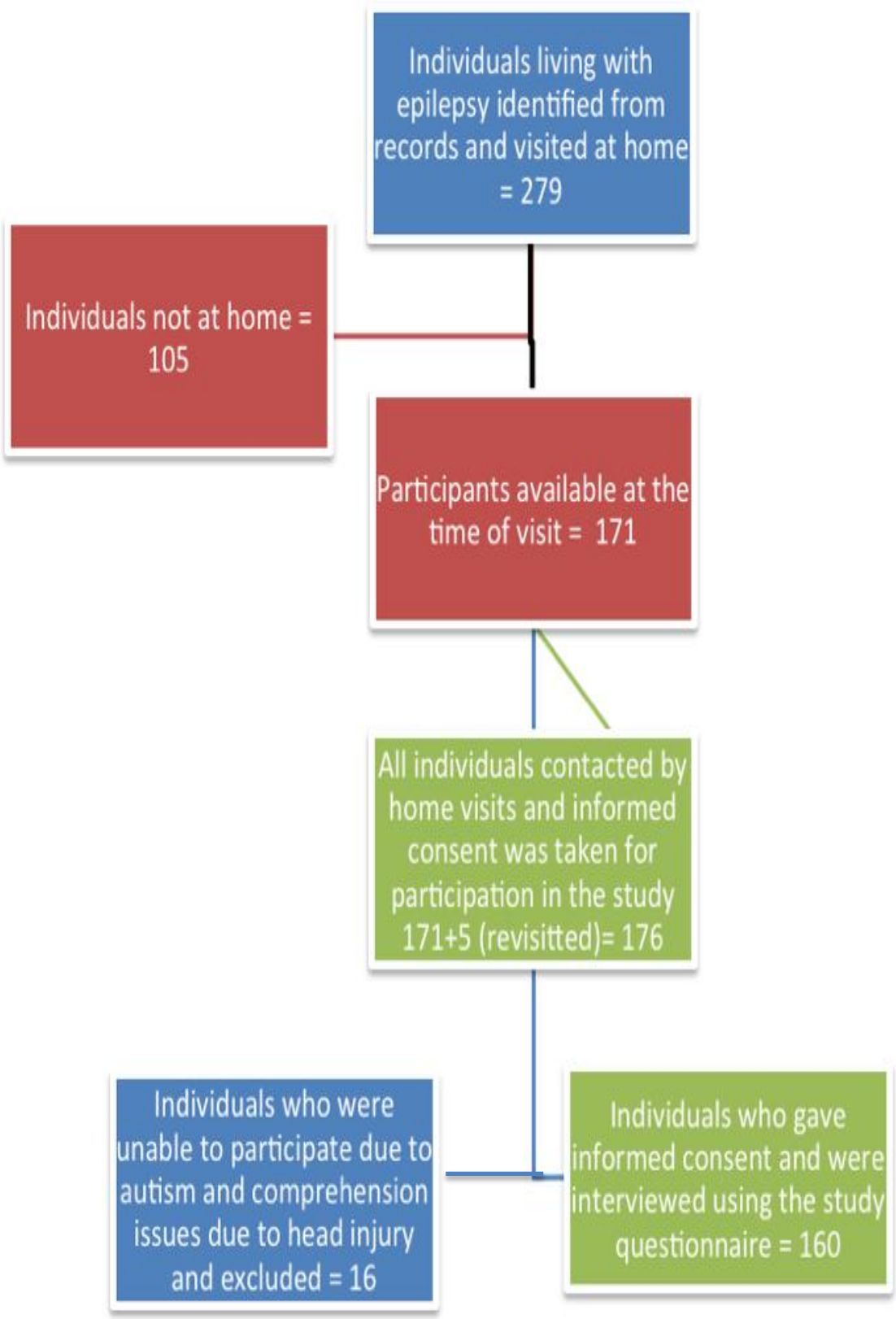
An informed consent (Annexure 1,3) was taken from the participant after explaining in the local vernacular (Tamil) about the study objectives, benefits that they and the community on a larger scale would obtain by taking part in the study. An information sheet was also provided for future reference along with the contact details of the principal investigator. The consent was obtained either in the form of a signature or the left thumb impression in cases where the participant was illiterate.

5.10 Study procedure.

The participants were interviewed at home, by the study investigator accompanied by the health aides of respective villages, using an interviewer administered pilot tested questionnaire in Tamil. The main outcome measure, quality of life was assessed using Quality of Life in Epilepsy- 31(QOLIE-31) questionnaire. A previously validated Tamil version of the questionnaire was used. The presence of anxiety and depression was assessed using the Generalized Anxiety Disorder-7 (GAD-7) and the Participant Health Questionnaire-9 (PHQ-9). Disease related factors such as medication side effects were assessed using the Liverpool Adverse Effects Profile (LAEP), and the seizure severity was assessed using Seizure Severity Questionnaire (SSQ). All the potential study participants were visited at least once, and then revisited till required sample size was reached.

5.11 : Algorithm of the study

Figure 1 Detailed diagrammatic Algorithm of study



5.12 Study tool

The study tool was a questionnaire consisting of questions related to social, economic, demographic, seizure related questions. Scores were computed for Seizure severity questionnaire (SSQ), Liverpool Adverse Effects Profile (LAEP) questionnaire, Generalized Anxiety Disorder-7 (GAD-7), Patient Health Questionnaire-9 (PHQ-9) and Quality Of Life In Epilepsy (QOLIE) score.

Seizure severity questionnaire (SSQ)

The seizure severity questionnaire is a validated self and observer rated evaluation of the severity of seizures. It was first described in 1999 and evaluated for validity and reliability in 2002. It is used to also assess the changes in seizure severity before and after treatment. The instrument has three main components - assessment of aura before seizures; during the seizure itself and post seizure cognitive, physical and emotional effects. It also includes questions regarding the changes in the severity post treatment, and the most distressing part of the seizure as reported by the patient. The scores range from 1 to 7, with higher scores indicating higher intensity and botheration. This scale has been used in large-scale studies to evaluate the effectiveness of treatment of various types of seizures including partial, complex seizures. The cut offs used in the current study was the median value of the score, wherein a value of 3 or higher was considered as more severe, and less than 3 were considered as less severe.(75–77)

The Liverpool Adverse Effects Profile (LAEP)

Epilepsy management relies heavily on use of several anti-epileptic medications like phenytoin sodium, sodium valproate and phenobarbitone. Each of these medications and their combinations has well documented side effects. These side effects can lead to discomfort and even death among patients. The patients themselves may be unaware that their symptoms are linked to their medications, and may not always report the presence of side effects to the treating physicians. The Liverpool Adverse Effects Profile evaluates the presence of each of the possible adverse effects of the medications through a Likert's scale with options being never a problem; rarely a problem; sometimes a problem and always or often a problem. There are nineteen items on the LAEP scale, so a minimum score of 19 and a maximum score of 76 are possible. This scale has been translated into other languages like Chinese and its validity and reliability tested. For this scale, the cut off used was the median value to divide the respondents into minimal and severe adverse effects.(78,79)

Generalised Anxiety Disorder-7 (GAD-7)

Generalised Anxiety Disorder-7 is a scale that has been tested and validated in multiple languages for the diagnosis of anxiety disorders. The scale has seven questions and a minimum score of 0 to a maximum score of 21. The cut off for the diagnosis of anxiety disorders are 5,10 and 15, which represent the cut offs for mild moderate and severe anxiety disorders. A score of 3 or more has been used in this study, which is suggestive of a condition needing intervention.(80)

Patient Health Questionnaire-9 (PHQ-9)

Patient Health Questionnaire-9 was derived from the Primary Care Evaluation of Mental Disorders (PRIME-MD) questionnaire assessing the presence of depression in patients. There are nine questions in this instrument, each with possible score ranging from 0 to 3. The total score thus ranges from 0 to 27. The score cut offs of 5 and above denote depression. The score between 5-9 corresponds to mild, 10 to 14 moderate, 15-19 moderately severe and 20-27 severe depression. All scores of 10 and above require active interventions.(81)

Health related quality of life (HRQOL)

HRQOL, the main outcome variable was assessed using the Quality Of Life In Epilepsy-31 (QOLIE 31). This is an instrument, which evaluates the patient reported quality of life, as related to epilepsy. The components evaluated include the overall health related and patient perceived quality of life currently, the cognitive and emotional effects of seizures, the reported seizure worry and anxiety, the medication effects, the social and occupations limitations faced by the individual, and the changes in the energy and fatigue levels of the participants. The weighted score for each component is calculated out of 100. The value of 50 is used to define poor or good score. Then the weighted averages are combined to form the total quality of life score.(66,81)

Other variables included in the questionnaire included, socio demographic variables like age, gender, marital status, education, monthly income, occupation, literacy and socioeconomic status as per Kuppusamy classification

into upper, upper middle, lower middle, upper lower and lower class. (2014).(83)

Kuppusamy SES classification is one of the most widely used classifications for assigning socio-economic status to individuals in studies in India. The classification uses education of head of household, occupation of head of household and total monthly family income to decide the socio-economic status of the individual. The income component of the scale is updated regularly to reflect the current Consumer Price Index (CPI).(83)

The components and score for the components are presented in table 1.

Table 1: Kuppusamy classification of socioeconomic status

	Score
Education	
Profession or honours	7
Graduate or post graduate	6
Intermediate or post high school diploma	5
High school certificate	4
Middle school certificate	3
Primary school certificate	2
Illiterate	1
Occupation	
Profession	10
Semi-profession	6
Clerical, shop-owner, farmer	5
Skilled worker	4
Semi-skilled worker	3
Unskilled worker	2
Unemployed	1
Family income per month (in Rs.)	
≥2000	12
1000-1999	10
750-999	6
500-749	4
300-499	3
101-299	2
≤100	1
Socioeconomic class	
Upper	26-29
Upper middle	16-25
Lower middle	11-15
Upper lower	5-10
Lower	0<5

Source: Oberoi SS(83).

Table 2: Modified income in Kuppusamy scale (2014)

Income (as per 2014 CPI)	Score
Rs. 1865 or less	1
Rs. 1866 to 5546	2
Rs. 5547 to 9248	3
Rs. 9249 to 13497	4
Rs. 13874 to 18497	6
Rs. 18497 to 36996	10
Rs. 36997 and above	12

Source: Oberoi SS(83).

The seizure related variables included were time since first seizure, age at diagnosis, time since last seizure, number of seizures over preceding six months, number of medications, presence of family history of seizures and the relationship with the participant, presence of co-morbidities and medications for the same.

5.13 Data entry

All the data was entered into Epidata software version 3.1 and analysed using SPSS for Windows, version 16.

5.14 Data analysis

The continuous variables were described with measures of central tendency and dispersion and as categorical data**:**

a. Age: in completed years was analysed as a categorical variable,
b. Education, (in completed years) was analysed as a categorical variable
c. Years of illness, (in completed years) was analysed as a categorical variable
d. Occupation was divided into working (including household work), not working
e. Average monthly income was categorised into two categories using median values
f. Marital status was categorised as single, married, separated/divorced
g. Socio-economic score was measured using Kuppuswamy scale(83) and was categorised into two groups.
h. Number of medications was divided into two categories on medications versus not on medication and then analysed
i. Type of seizure and aetiology of seizure was analysed as the focal or generalised seizures, with known aetiology versus unknown aetiology
j. Number of seizures over last six months was divided into no seizure, one or more number of seizures
k. Presence of co-morbidities was categorised into present or absent
l. Seizure Severity Questionnaire (SSQ) was analysed as categorical variable using the median score (3) as cut off.

m. Liverpool Adverse Effects Profile (LAEP) was analysed as categorical variable using 29 (median value) as cut off.

n. Generalised Anxiety Disorder-7GAD-7) was analysed as no anxiety (score 0), anxiety present (score 1 or more).

o. Patient health questionnaire-9 was analysed as no depression (score 0), depression present (1 or more)

p. QOLIE-31 was analysed after converting raw scores into percentages to get final score.(81). For categorical analysis, the median score value of 69 was used. The mean score and standard deviation were also calculated.

a. Bivariate analysis

All the explanatory variables were converted into categorical responses and statistical associations with HRQOL were examined using Chi-square test and odds ratios (OR) with 95% confidence intervals (95% CI) Multi variate analysis.

Explanatory variables that were either significant on bivariate analyses or those identified in the literature as strong predictors were included in the multivariate logistic regression analyses to examine associations after adjusting for the effects of confounding.

6 Results

A total of 160 individuals participated in the study. There were no refusals to participate. However there were 16 individuals who could not respond to the questions asked due to autism and comprehension problems (Figure 1).

6.1 Description of study participants

Table 3: Age distribution of study participants (N = 160)

Age groups	Frequency	Percentage
18 to 29 years	37	23.1
30 to 39 years	45	28.1
40 to 49 years	35	21.9
50 to 59 years	21	13.1
60 to 69 years	13	8.1
70 to 79 years	7	4.4
80 years and above	2	1.3

As can be seen from the above table 3, majority (45, 28.1%) of the respondents were in the age groups of 30 to 39 years, followed by 37 (23.1%) in the age group of 18 to 29 years. There were 35 (21.9%) respondents who were in the age group of 40 to 49 years. Thus the mean age of study participants was 40.6 years with a median of 38.5 years. The standard deviation was 14.87 years. The

oldest participant was 85 years old, while the youngest was aged eighteen years.

Table 4: Gender distribution of respondents (N = 160)

Gender	Frequency	Percentage
Male	76	47.5
Female	84	52.5

The gender distribution was almost equal, with a slightly higher number of females (84, 52.5%) than males (76, 47.5%) in the study population.

Table 5: Education level of study participants (N = 160)

Variable	Categories	Frequency	Percentage
Education	No schooling	37	23.1
	Primary school	4	2.5
	Middle school	56	35.0
	High school certificate	32	20.0
	Higher secondary certificate	21	13.1
	Graduate and above	10	6.2
Literacy	Literate	118	73.8
	Illiterate	42	26.3

Education is the number of years of formal schooling that the participant has completed, while literacy is the ability to read and write, that the individual has gained. As can be seen from Table 5, majority of the respondents were literate

(n = 118, 73.8%). Seventy four per cent (n = 119) of the respondents had completed middle school and above, and were confident of their ability to read and write in Tamil. Ten (6.1%) individuals had completed their graduation. There were 37 (23.1%) respondents who did not have any formal schooling. Among the 76 men, 60 (78.9%) were literate compared to 58, (69%) of the women, although this difference was not statistically significant by Chi-square test (p = 0.155). More men than women had completed high school (30.3% to 10.7%) and as a whole, men were better educated than females.

Table 6: Distribution of occupation by gender (N = 160)

Categories	Count	Males	Females
Housewife	57	0	57 (67.9%)
Not working	38	20 (26.3%)	18 (21.4%)
Farmer	10	10 (13.2%)	0
Coolie	10	8 (10.5%)	2 (2.4%)
Student	7	5 (6.6%)	2 (2.4%)
Mason	4	3 (3.9%)	1 (1.2%)
Shopkeeper	5	4 (5.3%)	1 (1.2%)
Sweeper	4	3 (3.9%)	1 (1.2%)
Retired	3	3 (3.9%)	0
Brick maker	2	1 (1.3%)	1 (1.2%)
Herder	2	1 (1.3%)	1 (1.2%)
Others	18	18 (23.7%)	0

The majority (n = 86) of the participants were involved in low wage occupations, like household and unskilled labour work. Seven individuals were availing disability pension and thus had a regular source of income.

The majority of women were housewives i.e. n = 57, 67.9%. About 18 (21%) of the women also reported not working, as compared to 20 (26%) of the men. Other occupations that participants were involved in included bank officer, karate teacher, engineer, flower seller, electrician, and carpenter.

Table 7: Type of family, family size and marital status of participants

(N = 160)

Variable	Categories	Frequency	Percentage
Type of family	Nuclear	100	62.5
	Joint	60	37.5
Family size	1 to 4	102	63.8
Mean (SD) = 4	5 to 9	54	33.8
(2.08) members	More than or equal to 10	4	2.5
Marital status	Married	100	62.5
	Single	51	31.9
	Separated	9	5.6

Nuclear families (100, 65.2%) were the commonest type of household seen, with a mean family size of 4 members (SD 2.08). A hundred and two (63.8%) individuals had a family size of less than 4. There were 6 participants who lived alone and the maximum family size was 14. There were 54 (33.8%)

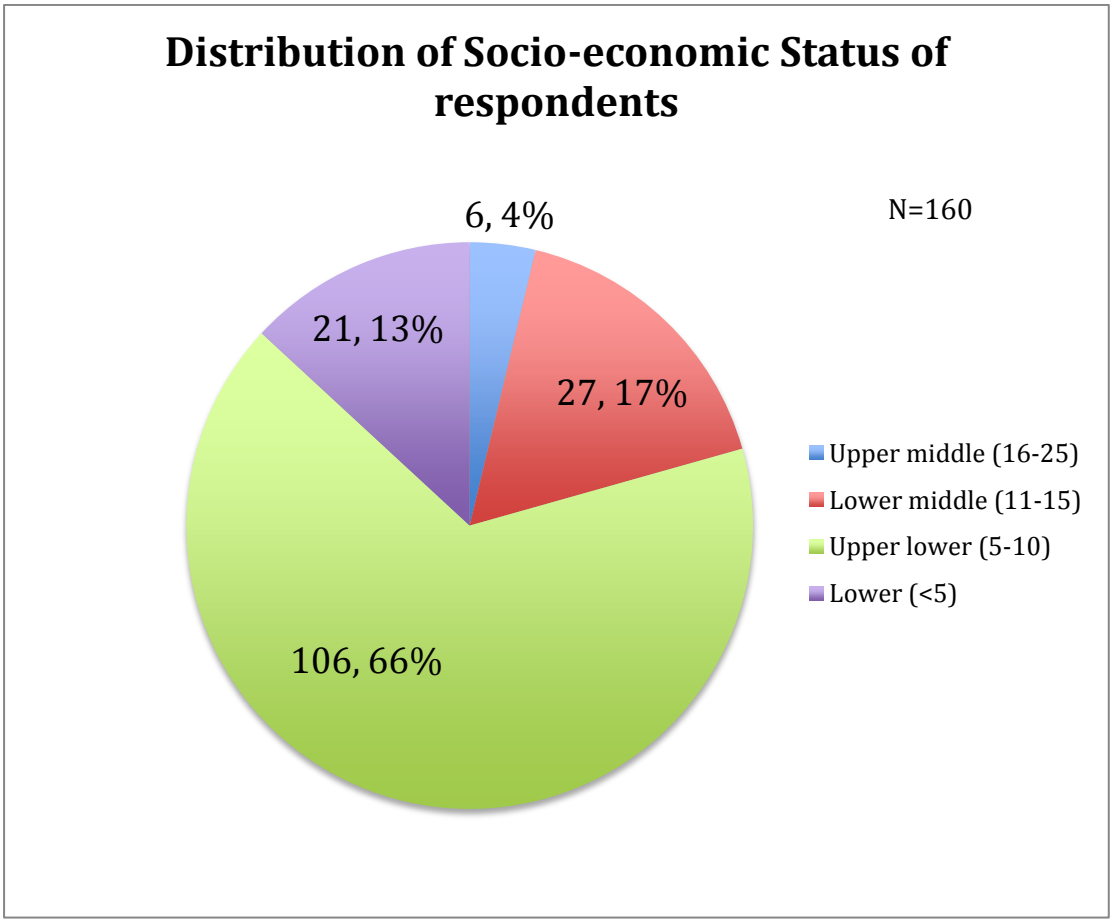
individuals who had 5 to 9 members in their family. Majority 100 (62.5%) of the participants were married. A significant number of participants had never married 51 (31.9%) and another 9 (5.6%) were separated from their spouse. There were no widowed or divorced subjects in the study population. More women 7 (8.3%) were separated then men 2 (2.6%). However, more men were single than women with 31 men (40.8%) as compared to 20 (23.8%) women who were single.

Table 8: Socioeconomic status of participants (as per modified Kuppuswamy classification 2014)

Variable	Categories	Frequency	Percentage
Total monthly income of family	Rs. 1,865 or less	31	19.4
	Rs. 1,866 to 5,546	50	31.3
	Rs. 5,547 to 9,248	35	21.9
	Rs. 9,249 to 13,497	25	15.6
	Rs. 13,874 to 18,497	14	8.7
	Rs. 18,497 to 36,996	5	3.1
	Rs. 36,997 and above	0	0
Socio-economic Status (SES)	Upper middle (16-25)	6	3.8
	Lower middle (11-15)	27	16.9
	Upper lower (5-10)	106	66.3
	Lower (<5)	21	13.1

The income categories were as per modified Kuppuswamy classification for the year 2014. There were no participants whose family income was more than Rs. 36,997 per month. Majority 106 (66.3%) of the respondents belonged to the upper lower class and no participant was from the upper class. There were 6 (3.8%) participants from the upper middle class, 27 (16.9%) from the lower middle class, 21 (13.1%) from the lower class (Figure 2; Table 8). There were 50 individuals (31.3%) whose income was between Rs. 1,866 to Rs. 5,546. There were 116 individuals (72.6%) whose monthly family income was less than Rs. 10,000. There were 5 individuals (3.1%) whose family monthly income was more than Rs. 18,000.

Figure 2: Distribution of socioeconomic status of respondents (N = 160)



6.2: Description of Seizure related characteristics of respondents

Table 9: Age at first onset of seizures and duration of illness (N = 160)

Variable	Categories	Frequency	Percentage
Age at onset of seizures	5 years and lower	32	20.0
	6 to 10 years	16	10.0
	11 to 15 years	30	18.8
	16 years and more	82	51.3
Duration since first episode of illness	5 years and lower	23	14.4
	6 to 10 years	23	14.4
	11 to 15 years	15	9.4
	16 years and more	99	61.9

Most 82 (51.3%) of the participants were diagnosed to have seizure disorder in adulthood. Among the participants 99 (61.9%) had the first seizure more than 16 years back. Only 32 (20%) had early childhood onset of seizures. There were 16 (10%) individuals who developed epilepsy during the age of 6-10 years. There were another 30 (18.8%) of individuals who developed epilepsy during early adolescence. Twenty-three (14.4%) of the participants were diagnosed to have seizure disorder in the last five years. 23 (14.4%) were diagnosed to have seizure disorder between 6 to 10 years back and 15 (9.4%) who were diagnosed to have epilepsy between 11 to 15 years back (Table 9).

Table 10: Seizure control related factors (N = 160)

Variable	Categories	Frequency	Percentage
Number of medications currently taking	Nil	46	28.8
	1	58	36.3
	2	45	28.1
	3 and more	11	6.9
Seizures activity in last 6 months	No episodes	95	59.4
	1 to 6 episodes	58	36.3
	More than 7 episodes	7	4.4
Time since last seizure episode	Less than 6 months	65	40.6
	6 months to 24 months	32	20.0
	More than 24 months	63	39.4

About 46 (28.8%) of respondents were not on any medications. Majority of respondents were on a single medication 58 (36.3%), while 11 (6.9%) were on three or more medications to control their seizures. The medications being used were Phenytoin, Phenobarbitone, Valproate and Carbamazepine. There were 95 (59.4%) individuals who did not have any seizures over the last 6 months. There were 58 (36.3%) individuals who had one to six episodes over the last six months. There were 7 (4.4%) individuals who had 7 or more episodes of seizures over the last 6 months. Among the 95 (59.4%) who did not have a seizure in the past six months. Sixty-three (39.4%) had a seizure episode more

than 2 years back. Thirty-two (20%) individuals had a last seizure episode between six to twenty-four months back.

Table 11: Distribution of comorbidities among participants (N = 160)

Variable	Categories	Frequency	Percentage
Co-morbid conditions	Absent	122	76.3
	Present	38	23.8
Type of illness	Diabetes alone	3	7.9
	Hypertension alone	2	5.3
	Others	16	42.1
	Multiple co-morbidities	17	44.7

The participants reported presence of co-morbidities in 38 (23.8%) of the cases. Diabetes mellitus was the commonest co-morbid condition. Majority 17 (44.7%) of the respondents had multiple co-morbidities. Among the other co-morbidities psychiatric illness like schizophrenia were present. There were two individuals (5.3%) with hypertension alone and 3 (7.9%) with diabetes alone. Sixteen (42.1%) individuals had other co-morbidities like stroke, rheumatic heart disease, schizophrenia and hypothyroidism.

Figure 3: Distribution of comorbidities among participants

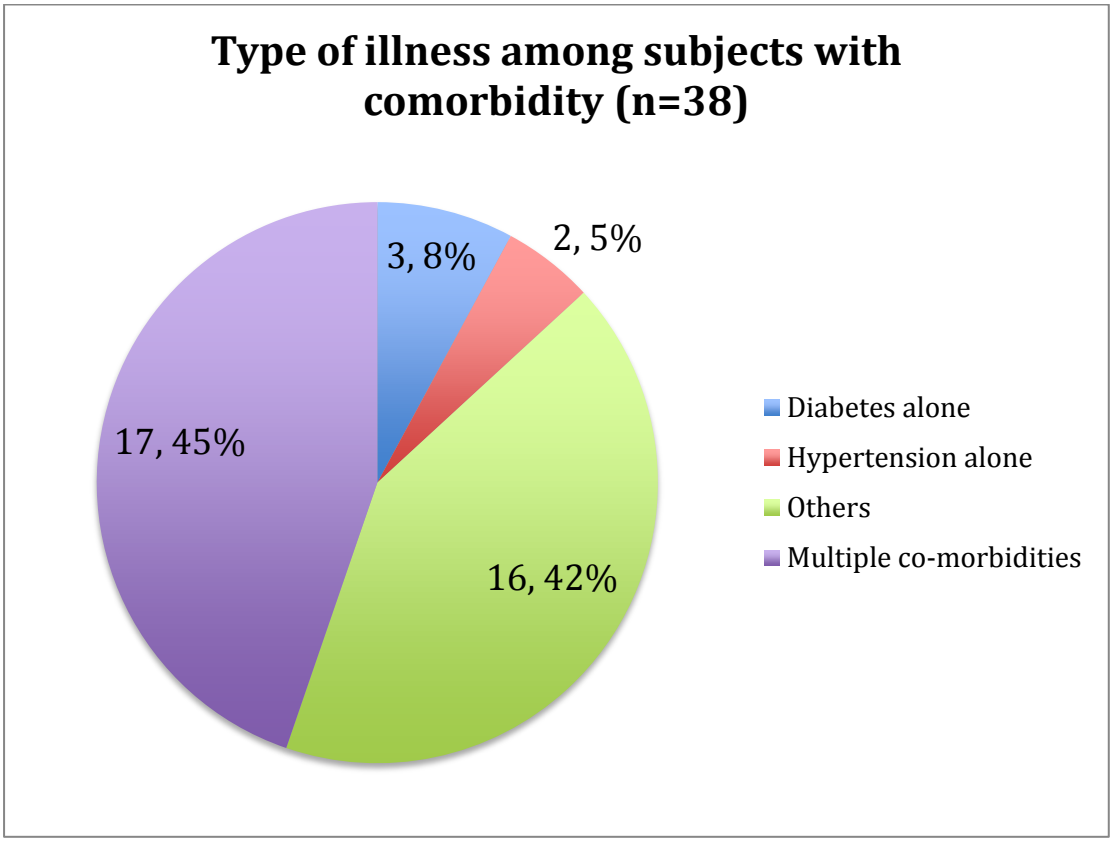


Table 12: Type of seizure and aetiology (N = 160)

Variable	Categories	Frequency	Percentage
Type of seizures	Generalized tonic clonic seizures (GTCS)	148	92.5
	Absence seizures	11	6.9
	Partial seizures	1	0.6
Etiology	Unknown	124	77.5%
	Post trauma	14	8.7%
	Others	13	8.1%
	Neurocystecercosis	9	5.6%

Among the respondents 148 (92.5%) had generalised tonic clonic seizures. Absence seizures were found in eleven (6.9%) individuals. One individual (0.6%) gave a history of partial seizure. The commonest known cause reported was post traumatic 14 (8.7%). Neurocysticercosis was the next most common cause with 9 (5.6%) respondents giving positive history. The most common aetiology reported was unknown, but only 5 individuals said that they had never been investigated for cause of seizures.

Figure 4: Distribution of the respondents by type of seizures (N = 160)

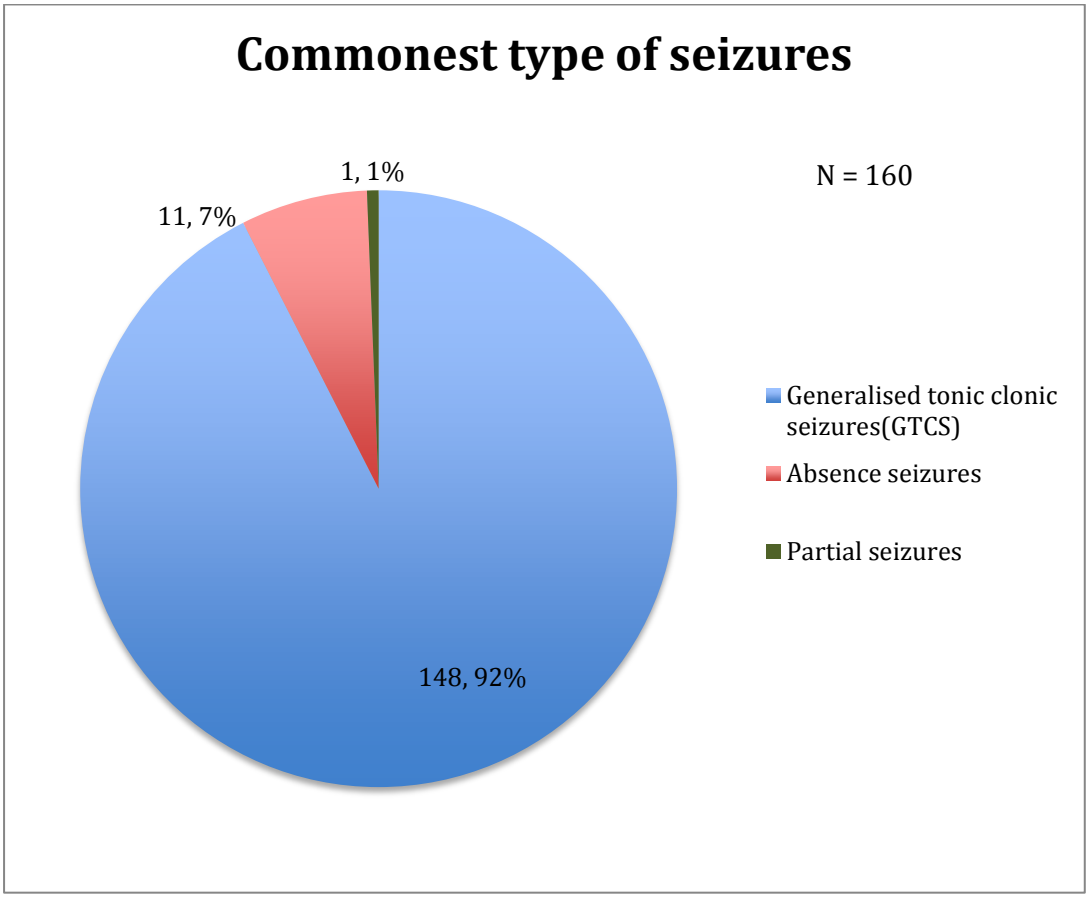


Table 13: Family history of epilepsy among participants (N = 160)

Variable	Categories	Frequency	Percentage
Family history of seizures	Absent	138	86.3
	Present	22	13.8
Relationship to participant (n = 22)	First degree	16	72.7
	Others	6	27.3

Family history of seizure disorder was present in 22 (13.8%) of the respondents. Out of which 16 (72.7%) was in first-degree relatives like parents or siblings. The other 6 (27.3%) relatives with history of seizures were cousins, grandparents, aunts and uncles.

6.3 Severity of seizures

As described in the methodology, severity of epilepsy was assessed using the seizure severity questionnaire (SSQ).

Figure 5: Participants response to the question' What is the most worrisome aspect of seizure?

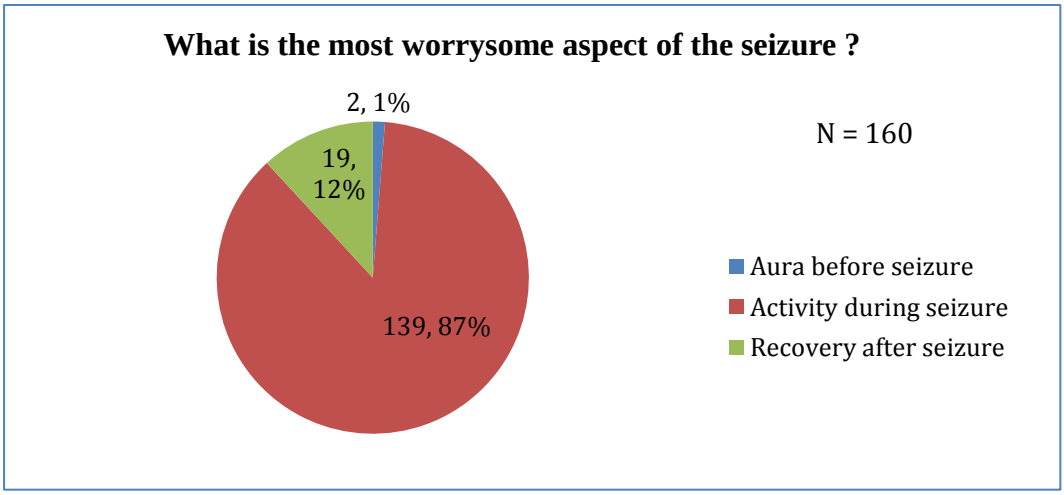


Table 14: Seizure Severity Questionnaire gateway questions (N = 160)

S. No.	Seizure severity questionnaire	No	Yes
1	Was there any aura before onset of seizure?	109 (68%)	51 (31.9%)
2	Did you have movements or actions during the seizure?	38 (23.8%)	122 (76.2%)
3	Did you only have altered consciousness during the seizure?	145 (90.6%)	15 (9.4%)
4	Did it take a while to recover after the seizure?	45 (28.1%)	115 (71.9%)
5	Did you have cognitive effects after the seizure?	67 (41.9%)	93 (58.1%)
6	Did you have emotional effects after seizure?	97 (60.6%)	63 (39.4%)
7	Did you have physical effects after seizure?	48 (30%)	112 (70%)

Table 15: Seizure severity score (N = 160)

Categories	Frequency	Percentage
Good (3 or less)	79	49.4%
Poor (more than 3)	81	50.6%

Among the 160 respondents, 139 (87%) reported that the activity during the seizure was the most distressing. Another 19 (12%) felt that the recovery after seizure was the most worrisome aspect. Only 2 (1%) individuals found the aura before the seizure the most distressing aspect (Figure 5).

Around 51 (31.9%) of the respondents had aura before the onset of seizure. To the question did you have movements or actions during the seizure 122 (76.2%) replied yes. Only 15 (9.4%) had altered consciousness during the seizure. A majority 115 (71.9%) reported that it took sometime to recover after the seizure. Among post seizure affects 93 (58.1%) reported cognitive effects, 63 (39.4%) reported emotional effects and 112 (70%) reported physical effects post seizures (Table 14). The mean seizure severity score was calculated as an average of the rating scales divided by the number of questions. The mean Seizure severity score was 2.85 with a standard deviation of 1.58, with a range from 0.13 to 5.67. The cut off for a good score was taken to be a score of 3 or lower. Using the cut off the respondents was divided in to good and poor categories with higher scores considered as poorer outcomes.

6.4 Liverpool Adverse Effects Profile (LAEP)

The Liverpool adverse effects profile describes the presence of adverse effects by their frequency of occurrence. It helps rate the severity of the adverse effects related to the use of anti-epileptic medications.

Table 16: Distribution of responses to Liverpool adverse effect profile scale (N = 160)

Adverse effects	Never a problem	Rarely a problem	Sometimes a problem	Always or often a problem
Unsteadiness	119 (74.4%)	11 (6.9%)	21 (13.1%)	9 (5.6%)
Tiredness	72 (45%)	21 (13.1%)	58 (36.2%)	9 (5.6%)
Hair loss	98 (61.2%)	34 (21.2%)	20 (12.5%)	8 (5%)
Skin problems	132 (82.5%)	9 (5.6%)	15 (9.4%)	4 (2.5%)
Weight gain	149 (93.1%)	1 (0.6%)	8 (5%)	2 (1.2%)
Depression	143 (89.4%)	5 (3.1%)	9 (5.6%)	3 (1.9%)
Disturbed sleep	118 (73.8%)	13 (8.1%)	18 (11.2%)	11 (6.9%)
Memory problems	95 (59.4%)	18 (11.2%)	37 (23.1%)	10 (6.2%)
Double or blurred vision	111 (69.4%)	18 (11.2%)	24 (15%)	7 (4.4%)
Sleepiness	114 (71.2%)	12 (7.5%)	27 (16.9%)	7 (4.4%)
Dizziness	132 (82.5%)	10 (6.2%)	16 (10%)	2 (1.2%)
Shaky hands	115 (71.9%)	20 (12.5%)	21 (13.1%)	4 (2.5%)
Trouble with mouth or gums	143 (89.4%)	7 (4.4%)	8 (5%)	2 (1.2%)
Restlessness	124 (77.5%)	18 (11.2%)	16 (10%)	2 (1.2%)
Difficulty concentrating	76 (47.5%)	29 (18.1%)	40 (25%)	15 (9.4%)
Feelings of anger or aggression towards others	62 (38.8%)	20 (12.5%)	60 (37.5%)	18 (11.2%)
Upset stomach	114 (71.2%)	21 (13.1%)	22 (13.8%)	3 (1.9%)
Headache	79 (49.4%)	33 (20.6%)	31 (19.4%)	17 (10.6%)
Nervousness or agitation	105 (65.6%)	19 (11.9%)	32 (20%)	4 (2.5%)

Figure 6: Distribution of responses to individual questions on LAEP scale (N = 160)

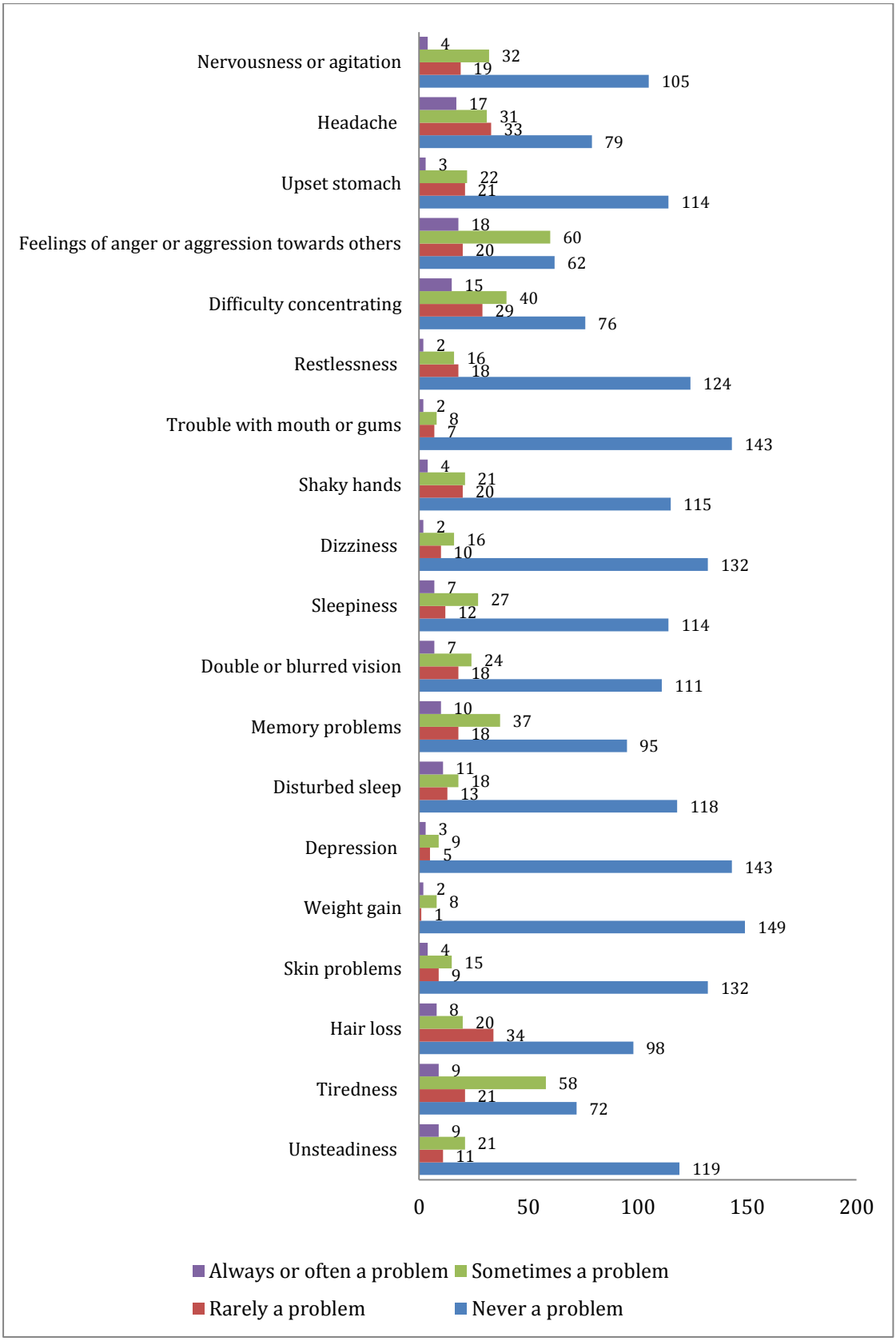


Table 17: LAEP scores classification (N = 160)

LAEP	Frequency	Percent
Good (less than 45)	156	97.5
Poor (45 or more)	4	2.5
Total	160	100

All of the respondents had some adverse event or the other. Though the numbers were small for each individual event, all of the participants had experienced some adverse effects. The commonest adverse events reported were feelings of anger or aggression which was reported by 18 (11.2%) individuals. tiredness 9 (5.6%), difficulty concentrating 15 (9.4%), and altered sleep patterns either decreased sleep 11 (6.9%) or increased sleep 7 (4.4%). The least common adverse event was weight gain with 11 (6.8%) individuals reporting weight gain. Unsteadiness was reported as always a problem by 9 (5.6%) of the respondents, sometimes a problem by 21 (13.1%) and rarely a problem by 11 (6.9%) of the respondents. Hair loss, was reported by 8 (5%) as always a problem, 20 (12.5%) as sometimes a problem, 34 (21.2%) as rarely a problem by respondents. Skin problems, were reported by a minority 9 (5.6%) as rarely a problem, 15 (9.4%) as sometimes a problem and 4 (2.5%) as always a problem. Depression or feeling of sadness was reported as always present by 3 (1.9%), sometimes by 9 (5.6%) and rarely by 5 (3.1%) of the respondents. Memory problems were reported to be always present by 10 (6.2%), sometimes

present by 37 (23.1%) of the respondents and rarely present by 18 (11.2%) of the respondents. Vision problems were reported to be present always by 7 (4.4%) sometimes present by 24 (15%) and rarely by 18 (11.2%) of the respondents. Dizziness was reported as always present by 2 (1.2%), sometimes present by 16 (10%) rarely present by 10 (6.2%) of the respondents. Shaky hands were reported as always present by 4 (2.5%), sometimes present by 21 (13.1.%) and rarely present by 20 (12.5%) of the respondents. Trouble with mouth or gums was reported to be always present by 2 (1.2%), sometimes present by 8 (5%) and rarely present by 7 (4.4%). Feelings of restlessness were reported to be always present in 2 (1.2%), sometimes present in 16 (10%) and rarely present in 18 (11.2%) of the respondents. Upset stomach was reported as always present in 3 (1.9%), sometimes present in 22 (13.8%) and rarely present in 21 (13.1%) of the respondents. The complaints of headaches were always present in 17 (10.6%), sometimes present in 31 (19.4%) and rarely present in 33 (20.6%) of the respondents. Feelings of nervousness and agitation were rarely present in 19 (11.9%), sometimes present in 32 (20%) and always present in 4 (2.5%) of the respondents.(Table 16, Figure 6.)

The mean score was 29.6 (SD 7.41) with a median of 29. The minimum score obtained was 19 and the maximum was 61. Majority 156 (97%) of the respondents had a good score (less than 45) as presented in table 17.

6.5 Generalised Anxiety Disorders

The presence of anxiety disorders was assessed using the Generalised Anxiety Disorders-7 (GAD-7) scale.

Table 18: GAD-7 (N = 160)

Anxiety	Frequency	Percentage
Nil (0)	85	53.1
Mild (1 - 5)	47	29.4
Moderate (6 - 10)	25	15.6
Severe (>/= 11)	3	1.9

The rating of anxiety disorders was as per previously published guidelines. About half 75 (46.9%) the interviewed participants had some form of anxiety disorders. Most were mild 47 (29.4%) with no need for active intervention, but about 28 (16.6%) needed active management of their anxiety disorder. The mean score for GAD-7 was 2.33 (SD 3.5), with the median and mode of zero.

6.6 Patient Health Questionnaire-9 (PHQ-9)

The patient health questionnaire has 9 questions and was used for evaluating the presence of depression in the respondents. The mean score was 2.3 (SD 4.5). The median and mode were 0.

Table 19: Patient Health Questionnaire-9 (N = 160)

Depression	Frequency	Percentage
Nil (0)	95	59.4
Minimal (1 - 4)	37	23.1
Mild (5 - 9)	15	9.4
Moderate (10 - 14)	9	5.6
Moderately severe (15 - 19)	1	0.6
Severe (20 - 27)	3	1.9

Ninety-five (60%) of the respondents did not have any form of depression. The majority 37 (23.1%) had minimal depression. Nine participants (5.6%) had moderate depression and one (0.6%) had moderately severe depression. The 3 participants who had severe depression also had a death in the close family within the last six months.

6.7 Quality of life in epilepsy (QOLIE-31) scores

The participant related scores over the quality of life in epilepsy domains was converted into a 0-100 point scale and then weighted average was calculated using the guidelines provided with the scale.

Figure 7: Formula for calculation of QOLIE-31 scores

FORMULA FOR CALCULATING QOLIE-31 OVERALL SCORE

QOLIE-31 Scale	Final Scale Score		Weight		Subtotal
Seizure worry	____	×	.08	=	____ (a)
Overall quality of life	____	×	.14	=	____ (b)
Emotional well-being	____	×	.15	=	____ (c)
Energy/fatigue	____	×	.12	=	____ (d)
Cognitive functioning	____	×	.27	=	____ (e)
Medication effects	____	×	.03	=	____ (f)
Social functioning	____	×	.21	=	____ (g)
OVERALL SCORE: Sum subtotals (a) through (g)				=	____

Source: QOLIE31_ scoring.pdf, from www.rand.org

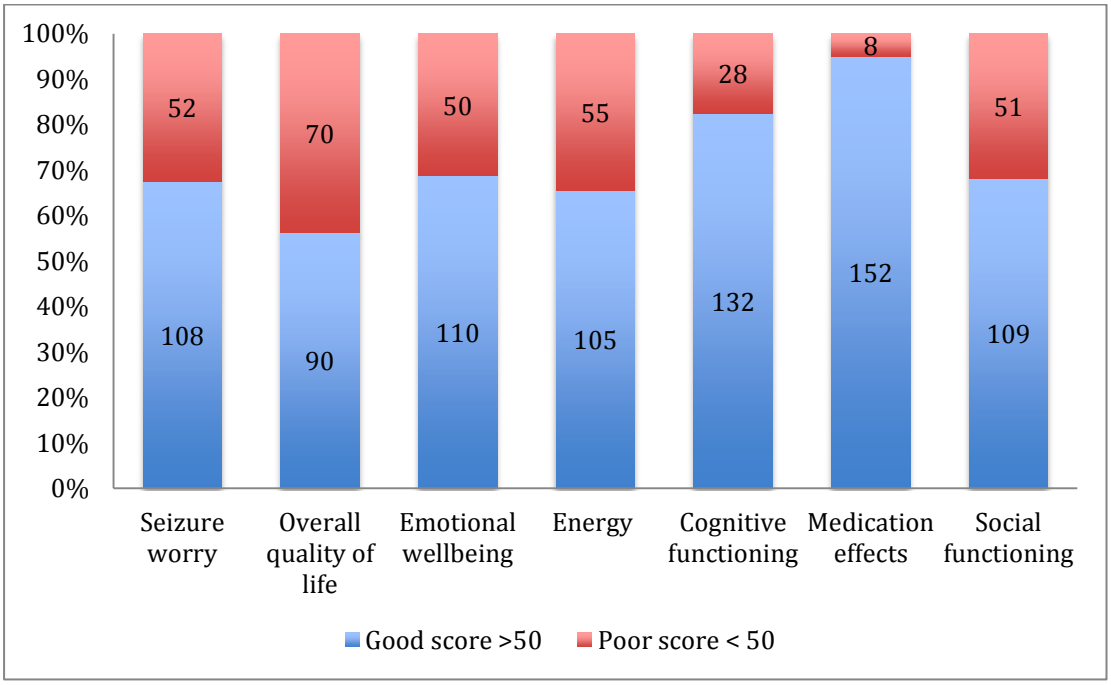
Table 20: Distribution of components of QOLIE-31 scores

	Medi-cation effects	**Quality of life**	**Seizure worry**	**Cognitive functioning**	**Social function**	**Emotion**	**Energy**	**Total QOLIE value**
Mean (S.D)	91.96 (17.55)	58.92 (23.19)	67.32 (27.44)	76.83 (27.27)	54.22 (9.47)	62.57 (25.71)	60.75 (28.75)	65.20 (16.37)
Median	100	60	85	90.83	60	68	70	68.85
Mode	100	77.5	85	100	60	92	80	82.45
Minimum	8.33	17.5	0	3.33	20	4	0	21.09
Maximum	100	100	100	100	72	100	100	88

Each component of the quality of life scale had an overall maximum possible score of 100. For each component a score of 50 was taken as the cut off for categorizing individuals into those that had good quality of life (score above 50) and poor quality of life (score less than and including 50). The mean score was lowest for the component of social functioning with a mean score of 54.22 (9.47). The mean score obtained for the medication effects component of 91.96 (17.55). The self reported quality of life had a mean score of 58.92 (23.19). The component of seizure worry had a mean score of 67.32 (27.44). The cognitive functioning component had a mean score of 76.83 (27.27) the social functioning component had a mean score of 54.22 (9.47). The emotional well being components had a mean score of 62.57 (25.71). The energy fatigue component had a mean score of 60.75 (28.75).(Table 20)

The total quality of life mean score was 65.20, (16.37) median score was 68.85 and mode was 82.45. The minimum score obtained was 21.09 and the maximum score was 88.

Figure 8: Distribution of QOLIE-31 components score (N = 160)



When absolute values were used as cutoffs, the distribution of the components of the QOLIE-31 score show that the medications effects component was best with more than 152 (95%) participants scoring more than 50. The overall patient reported quality of life score was reported as good by 90 (58%) individuals (Figure 8).

***6.8 Bivariate Analysis**:*

All the explanatory variables were recoded into two categories and the median calculated total quality of life score was used to categorize individuals into having good and poor quality of life.

Table 21: Bivariate analysis: Socio-demographic factors and QOLIE-31 scores (N = 160)

Variable	Categories	Poor QOLIE-31 scores (<69)	Good QOLIE-31 scores (>69)	Chi-square p value	Odds ratio (95% Confidence Interval)
Age	Less than 39 years	40 (48.8%)	42 (51.2%)	0.752	0.905 (0.487-1.682)
	More than 39 years	40 (51.3%	38 (48.7%)		
Gender	Male	34 (44.7%)	42 (55.3%)	0.205	0.669 (0.358-1.248)
	Female	46 (54.8%)	38 (45.2%		
Marital status	Single	30 (50%)	30 (50%)	1	1 (0.527-1.897)
	Currently married	50 (50%)	50 (50%)		
Literacy	Illiterate	21 (50%)	21 (50%)	1	1 (0.494-2.022)
	Literate	59 (50%)	59 (50%)		
Occupation	Not working	24 (63.2%)	14 (36.8%)	0.063	2.020 (0.955-4.274)
	Working	56 (45.9%)	65 (54.1%)		
Income	No income	49 (52.1%)	45 (47.9%)	0.521	1.229 (0.654-2.309)
	Any income	31 (47%)	35 (53%)		
SES (Kuppusamy scale 2014)	Lower class	72 (56.7%)	55 (43.3%)	0.001	4.091 (1.714-9.765)
	upper and lower middle class	8 (24.2%)	25 (75.8%)		
Type of family	Nuclear	53 (53%)	47 (47%)	0.327	1.378 (0.725-2.621)
	Joint	27 (45%)	33 (55%)		

When age was categorized as less than 39 and more than 39 years 40 (48.8%) to 40 (51.3%) individuals in each respective category had poor quality of life and this difference was not statistically significant (p = 0.752).

Females 46 (54.8%) had poorer quality of life as compared to 34 (44.7%) of males (p = 0.205).

The quality of life was similar 50% among those currently single 30 (50%) versus those currently married 50 (50%). When the illiterate respondents were compared to the literate respondents the quality of life was similar in both the groups.

Among those not working 24 (63.2%) reported a poorer quality of life as compared to working individuals amongst whom 56 (45.9%) reported a poorer quality of life (p = 0.063). Amongst those who had no income 49 (52.1%) reported poorer quality of life as compared to those with any income 31 (47%) reported poorer quality of life (p = 0.521).

Amongst people from the lower class, 72 (56.7%) reported poorer quality of life, as compared to the middle class, in which, 8 (24.2%) individuals reported poorer quality of life and, this difference was statistically significant (p = 0.001) and people from the lower class having four (95% CI 1.7 - 9.8) time higher odds as compared to the middle class for having poor quality of life.

People in nuclear 53 (53%) families had slightly higher proportions of poorer quality of life as compared to those in joint 27 (45%) families. However, this difference was not statistically significant (p = 0.327).

Table 22: Bivariate analysis: Seizure related factors and QOLIE-31 scores (N = 160)

Variable	Categories	Poor QOLIE-31 scores (<69)	Good QOLIE-31 scores (>69)	Chi-square p value	Odds ratio (95% Confidence Interval)
Duration of illness (since first episode)	5 years or less	11 (47.8%)	12 (52.2%)	0.822	0.903 (0.373-2.187)
	More than 5 years	69 (50.4%)	68 (49.6%)		
Age at onset	Less than 5 years	15 (46.9%)	17 (53.1%)	0.693	0.855 (0.394-1.858)
	More than 5 years	65 (50.8%)	63 (49.2%)		
Family history	Present	14 (63.6%)	8 (36.4%)	0.168	1.909 (0.753-4.842)
	Absent	66 (47.8%)	72 (52.2%)		
Number of medications	No	23 (50%)	23 (50%)	1	1 (0.504-1.983)
	One or more	57 (50%)	57 (50%)		
Type of seizure	GTCS	75 (50.7%)	73 (49.3%)	0.548	1.438 (0.437-4.738)
	All others	5 (41.7%)	7 (58.3%)		
Etiology	Unknown	60 (48.4%)	64 (51.6%)	0.449	0.750 (0.356-1.581)
	Known	20 (55.6%)	16 (44.4%)		
Co-morbid conditions	No	58 (47.9%)	63 (52.1%)	0.357	1.406 (0.680-2.907)
	Yes	22 (56.4%)	17 (43.6%)		
Time since last episode	24 months or less	55 (58.7%)	42 (43.3%)	0.035	1.990 (1.044-3.794)
	More than 24 months	25 (39.7%)	38 (60.3%)		
Number of seizures over 6 months	Any episode	38 (58.5%)	27 (41.5%)	0.077	1.776 (0.938-3.362)
	No	42 (44.2%)	53 (55.8%)		
Seizure severity score	SSQ Score Poor (more than3	55 (69.1%)	25 (30.9%)	<0.001	5.133 (2.620-10.056)
	SSQ Good (3 or less)	24 (30.4%)	55 (69.6%)		
Patient health questionnaire -9	Poor (1 and above)	53 (81.5%)	12 (18.5%)	<0001	11.123 (5.155-24)
	Good (0)	27 (28.4%)	68 (71.6%)		
Generalized anxiety disorder-7	Poor (3 and above)	42 (73.7%)	15 (26.3%)	<0.001	4.784 (2.349-9.767)
	Good (0)	38 (36.9%)	65 (63.1%)		
Liverpool adverse effects profile	Poor (29 or more)	60 (74.1%)	21 (25.9%)	<0.001	8.429 (4.144-17.144)
	Good (29 or less)	20 (25.3%)	59 (74.7%)		

In the analysis of various seizure related factors and the QOL, individuals in whom the duration of illness i.e. time since the first episode was less than 5 years 11 (47.8%) had a poorer quality of life. This difference was statistically not significant ($p = 0.822$).

Individuals whose age at onset was less than 5 years 15 (46.9%) had poorer quality of life as compared to those whose age at onset was more than 5 years 65 (50.8%). This difference was not statistically significant ($p = 0.693$).

Individuals with a positive family history 14 (63.6%) had a higher risk of having a poor quality of life as compared to those without a family history 66 (47.8%). This difference was not statistically significant ($p = 0.168$).

When individuals who were not on medication 23 (50%) were compared to those on medication 57 (50%) had similar risk for poor quality of life and p value was 1.

Individuals with GTCS 75 (50.7%) when compared to all other type of seizures 5 (41.7%) had similar risk for poor quality of life. ($p = 0.548$). When individuals with a known etiology 20 (55.6%) were compared to people with unknown etiology 60 (48.4%) the risk for having poor quality of life was not significantly different ($p = 0.449$).

Amongst the respondents with co-morbid conditions 22 (56.4%), as compared to respondents without co-morbid conditions 58 (47.9%) had poorer quality of life. Again this difference was also not statistically significant.($p = 0.357$).

Among individuals whose last seizure was within the last 24 months 55 (58.7%) had a poorer quality of life as compared to those whose last episode was more than

24 months back 25 (39.7%). The odds for having poor quality of life was 2 (1.04 - 3.79) times significantly higher (p = 0.035).

Individuals who had any episode of seizures 38 (58.5%) over the last 6 months had a higher odds of having poor quality of life as compared to those who did not have any seizures 42 (44.2%) in the last 6 months. (p = 0.077).

When the seizure severity score was dichotomized, into poor scores and good scores, individuals scoring more than 3 (55,69.1%) had a higher odds of having poor quality of life scores as compared to those with better seizure severity scores (24,30.4%). This difference was significant (p <0.001), and odds ratio of 5.133 (2.62 - 10.05).

Respondents with depression (PHQ-9) score of 1 and above (53, 81.5%) had a poorer quality of life as compared to those without depression (27, 28.4%). This difference was statistically highly significant with a p value of less than 0.001. People with depression had 11 (5.15 – 24) times higher odds of poor quality of life score as compared to people without depression.

Individuals with more anxiety 42 (73.7%) had a poorer quality of life as compared to individuals with less anxiety [p <0.001 and odds of 4.78 (2.35 – 9.8)]. Individuals with more adverse events 60 (74.1%) had 8.43 (4.14 – 17.14) more odds of having poor quality of life as compared to those with less adverse events 20 (25.3%).

Table 23:Explanatory variables significantly associated with HRQOL

(N = 160)

Variable	Categories	Poor QOLIE-31 scores (<69)	Good QOLIE-31 scores (>69)	Chi-square p value	Odds ratio (95% Confidence Interval)
SES (Kuppusamy scale 2014)	Lower class	72 (56.7%)	55 (43.3%)	0.001	4.091 (1.714-9.765)
	Upper and lower middle class	8 (24.2%)	25 (75.8%)		
Time since last episode	24 months or less	55 (58.7%)	42 (43.3%)	0.035	1.990 (1.044-3.794)
	More than 24 months	25 (39.7%)	38 (60.3%)		
Seizure severity score	Poor (3 and above)	55 (69.1%)	25 (30.9%)	<0.001	5.133 (2.620-10.056)
	Good	24 (30.4%)	55 (69.6%)		
Patient health questionnaire-9	Poor	53 (81.5%)	12 (18.5%)	<0.001	11.123 (5.155-24)
	Good (0)	27 (28.4%)	68 (71.6%)		
Generalized anxiety disorder-7	Poor (3 and above)	42 (73.7%)	15 (26.3%)	<0.001	4.784 (2.349-9.767)
	Good (0)	38 (36.9%)	65 (63.1%)		
Liverpool adverse effects profile	Poor (29 or more)	60 (74.1%)	21 (25.9%)	<0.001	8.429 (4.144-17.144)
	Good (29 or less)	20 (25.3%)	59 (74.7%)		

6.9 Multivariate analysis

Table 24: Multivariate analysis: Exposure factors and QOLIE-31 scores (N = 160)

Variable	Categories	Poor QOLIE-31 scores (<69)	Good QOLIE-31 scores (>69)	p value	Exp B (95% Confidence Interval)
Age	Less than 39 years	40 (48.8%)	42 (51.2%)	0.860	1.094 (0.403-2.966)
	More than 39 years	40 (51.3%	38 (48.7%)		
Gender	Male	34 (44.7%)	42 (55.3%)	0.956	0.973 (0.369-2.566)
	Female	46 (54.8%)	38 (45.2%		
Occupation	Not working	24 (63.2%)	14 (36.8%)	0.015*	4.526 (1.340-15.290)
	Working	56 (45.9%)	65 (54.1%)		
SES (Kuppusamy scale 2014)	Lower class	72 (56.7%)	55 (43.3%)	0.001*	11.201 (2.614-47.994)
	Middle (upper and lower) class	8 (24.2%)	25 (75.8%)		
Type of family	Nuclear	53 (53%)	47 (47%)	0.410	1.508 (0.568-4.007)
	Joint	27 (45%)	33 (55%)		
Time since last episode	24 months or less	55 (58.7%)	42 (43.3%)	0.331	1.833 (0.541-6.210)
	More than 24 months	25 (39.7%)	38 (60.3%)		
Co-morbid conditions	Yes	22 (56.4%)	17 (43.6%)	0.907	1.072 (0.335-3.429)
	No	58 (47.9%)	63 (52.1%)		
Family history	Present	14 (63.6%)	8 (36.4%)	0.502	1.586 (0.412-6.098)
	Absent	66 (47.8%)	72 (52.2%)		
Number of medications	No	23 (50%)	23 (50%)	0.202	2.261 (0.645-7.924)
	One or more	57 (50%)	57 (50%)		
Type of seizure	GTCS	75 (50.7%)	73 (49.3%)	0.769	1.354 (0.179-10.275)
	All others	5 (41.7%)	7 (58.3%)		
Seizure severity score	SSQ Score Poor (more than 3)	55 (69.1%)	25 (30.9%)	0.015*	3.823 (1.297-11.266)
	SSQ Good (3 or less)	24 (30.4%)	55 (69.6%)		
Patient health questionnaire-9	Poor (1 and above)	53 (81.5%)	12 (18.5%)	<0.001*	17.631 (4.549-68.327)
	Good (0)	27 (28.4%)	68 (71.6%)		
Generalized anxiety disorder-7	Poor (3 and above)	42 (73.7%)	15 (26.3%)	0.065	3.806 (0.920-15.744)
	Good (0-2)	38 (36.9%)	65 (63.1%)		
Liverpool adverse effects profile	Poor (29 or more)	60 (74.1%)	21 (25.9%)	0.001*	5.698 (1.952-16.638)
	Good (29 or less)	20 (25.3%)	59 (74.7%)		
.* significant association					

Explanatory variables that were either significant on bivariate analyses or those identified in the literature as strong predictors were included in the multivariate logistic regression analyses to examine associations after adjusting for the effects of confounding.

In the multivariate analysis, after adjusting for confounding factors, low socio economic status continued to be statistically significant with an adjusted odds ratio of 11.2 (2.6 - 47.99). Poor seizure severity score was significantly associated with poor quality of life with an adjusted odds ratio of 3.82 (1.28 – 11.27) The presence of depression among the study subjects, had a significant association with adjusted odds ratio of 17.63 (4.55 - 68.33). A higher Liverpool adverse effects score was also significantly associated with poor quality of life with an adjusted odds ratio of 5.7 (1.95 – 16.64). Presence of higher anxiety which was significant on bivariate analysis was no longer significantly associated with poor quality of life scores in the multivariate model with an adjusted odds ratio of 3.806 (0.920 - 15.74) All other factors like age ($p = 0.860$), gender ($p = 0.956$), type of family ($p = 0.41$), time since the last episode ($p = 0.331$), presence of co-morbid conditions ($p = 0.907$), presence of family history ($p = 0.502$), number of medications ($p = 0.20$) and type of seizures ($p = 0.77$) were not significantly associated with quality of life in the multivariate regression analysis.

7 Discussion

The aim of this study was to assess the quality of life of people with epilepsy in a rural community and to examine the factors associated with poor quality of life. Previous studies done in this area used non disease specific scales, like WHOQOL-BREF and found that the quality of life was poor among people with epilepsy.(71,72) This study attempted to evaluate if using disease specific scales like QOLIE-31 gave better understanding of the quality of the life of individuals. The rationale behind this was that, individuals with a particular condition, in this case epilepsy have distinct issues that influence their perception of their own quality of life.

The study population was above 18 years of age and ranged from 18 years to 85 years of age. Majority of the participants were in the age group of 30 to 39 years, which are the peak years for individuals to work and contribute to society and their families. The distribution of men and women was almost equal in the study population. However globally the prevalence of epilepsy is reported to be higher in men than women.(6) This could be possibly due to the fact that more men were unavailable at the time of the study, because of living in a different city or town for employment purposes. The education levels for the study population had about 23% who reported illiteracy or no schooling, which is slightly higher than the levels of literacy for Vellore district as reported in the 2011 census (79.17%). Majority of the female participants reported their occupation as housewives. There was more reported unemployment in men than women. The participants who were working reported a wide range of occupations. Income was reported as average monthly

income and ranged from none for housewives and unemployed individuals to Rs. 30,000. There were seven individuals who had access to social support measures like disability pension. While this is a small amount of money, it added to the financial security of the individual. There was high proportion of single people among the respondents. Majority of who lived in nuclear family structure. The family dynamics can influence the quality of life of individuals, possibly through expressed emotions and felt stigma.(50) The social economic status as measured by the Kuppusamy score, revealed that majority of the participants belonged to the middle and lower class. This score being a composite of monthly income of the family with education and occupation of the head of the family.(83)

The primary outcome measure was the quality of life. The QOL score has a maximum possible score of 100 and minimum of 0. In this study, the mean score was 65.20 (SD 16.37), which meant that a majority of individuals were satisfied with their health and level of activities. Other studies that have used the same scale in Africa, found similar results, in sub-Saharan region 64.2 (SD 13.6) and Uganda 58 (SD = 13).(28,85) Studies conducted in Vellore using WHO-BREF found a mean score of 59.49 (SD 12.3) and 61.49 (12.56).(71,72)

Gender did not significantly affect the QOL scores, with men (34, 44.7%) and women (46, 54.8%) having similar proportions of poor QOL scores, with a p value of 0.956 and odds ratio of 0.973 (0.369 - 2.566). This was different from other studies which found that women had poorer QOL scores.(42,72) A possible explanation for this could be that more women were married and were able to carry

out their daily activities successfully, as compared to men, who have to earn in order to fulfill their societal roles.

Older individuals aged 39 years and more (40, 51.3%) did not have significantly different [p = 0.860, OR = 1.094 (0.403 - 2.966)] scores as compared to younger individuals (40, 51.3%) in this study, unlike in a hospital based study which found that older individuals had poor QOL scores, possibly since elderly people seeking healthcare are usually sick, which could have an impact on their QOL.

The duration of illness also did not affect the QOL scores, with the proportion of individuals with poor scores similar in both people with less than 5 years 11 (47.8%) and more than 5 years 69 (50.4%) of illness, with p value 0.822 and odds ratio of 0.903 (0.373 - 2.187). Other studies from India had found that longer duration of disease was significantly associated with poor QOL scores, but again these studies were conducted in hospital settings where the individuals with more severe disease would be more.(61,67)

There was also no difference between those currently on medication (57, 50%), and those not on medication (23, 50%) with p value of 1 and odds ratio of 1 (0.504 - 1.983). In other studies from India the number of medications was associated with QOL scores.(66,68,69)

Among the illness specific factors evaluated in the study, significantly associated factors were age at first onset of seizure, the duration of illness and number of medications the participant was on currently. Around half the participants had first onset of seizures in adulthood. However, 61.9% had the illness for 16 years or more. One quarter of the participants were no longer taking medications, either they

had stopped on their own or were told they did not need any more medications due to the quiescent state of the condition. Two thirds of the respondents had not had a seizure episode, in the preceding six months before the study. Among these, another two thirds had a last seizure episode more than two years back, fitting the definition of inactive epilepsy. A majority of participants reported generalized tonic clonic seizures as the primary type of the seizure activity. Co- morbid conditions reported were mostly chronic diseases like diabetes and hypertension.

The Seizure severity questionnaire threw light on some interesting findings. Thirty two per cent of the respondents had experienced aura before a seizure and most found it helpful as they could prepare for the seizure episode by stopping work and getting to safety. According to the participants a majority (92%) had generalized seizures, but in the severity questionnaire only 75% reported falls or tonic clonic activity. This could be because of the cognitive effects associated with ictal activity in the patient. More than half of the participants had some cognitive impairment (93, 58.1%) in the post-ictal state. Majority of the participants reported physical symptoms like body ache and fatigue (112; 70%) in the post-ictal phase. A majority of the participants found the post seizure symptoms (139; 87%) the most distressing part of the illness. The higher seizure severity score was associated with poor quality of life, which is similar to other studies, where seizure severity and frequency was strongly associated with poor quality of life.(28,61)

The Liverpool adverse effects profile had low scores, indicating a low level of perceived adverse events due to anti-epileptic medications. Though there were no individuals without any adverse events, still the mean; SD (29; 7.94) median (29)

and mode (22) were close to the minimum possible score of 17. The commonest adverse events reported were anger and aggression towards others and headache. Other studies from Brazil had found the mean score to be 37.6 (SD = 13.35) and from Mexico to be 41.2 (SD = 11.8). (79,88,89) This difference could be due to the disparities in the settings.

The proportion of individuals with depression and anxiety were similar to other studies conducted across the world. Both depression and anxiety disorders were significantly associated with poor quality of life. The QOL scores are subjective and individuals who have anxiety or depression results in it influencing the QOL outcome through felt stress and perceptions of illness. (34,40,59,90,91,64)

Individuals who had a seizure episode in the last 24 months [55 (58.7%)] were almost two times more likely [OR 1.99 (1.044 - 3.794)] to have poor QOL scores than those with more than 24 months [25 (39.7%)] and this difference was statistically significant (p = 0.035). This finding is similar to other studies from India. (61,70,72)

Among people from the lower class, 72 (56.75%) had a poor quality of life score as compared to those from the middle class [8 (24.2%)] with a p value of 0.001 and odds ratio of 4.09 (1.714 - 9.765). The SES score is a composite of occupation, income, education of head of family and represents the opportunities and resources available to an individual. Other studies have had similar findings.(68,90)

When the Seizure severity scores were categorized into, high scores as poor and low scores as good, the proportion of respondents with poor QOL was 55 (69.1%) and 24 (30.4%) respectively. The p value was less than 0.001 and the odds ratio

was 5.133 (2.620 - 10.056). Other studies which have looked at the seizure severity have also found similar findings, and the seizure severity is one of the most strongly associated factors with QOL as it affects all aspects of the quality of life.(11,28)

The LAEP scores represent the amount and severity of adverse effects of medications, and thus poor scores among 60 (74.1%) of the participants as compared to good scores among 20 (25.3%) participants was significantly associated ($p < 0.001$) with poor QOL with up to 8 times more odds of poor QOL scores. Other studies from Asia and India have found that adverse effects of medications lead to changes in the QOL scores due to interference in daily activities.(11,88,89)

In the multivariate model, depression, lower socio-economic status, higher severity (SSQ), more adverse effects (LAEP), continued to be significantly associated with poor quality of life. The presence of depression demonstrated strongest association with poor quality of life and individuals who had any depressive symptoms were seventeen times more likely to report poor quality of life. This finding is similar to many other studies across India(44) and the world.(72)

Low socioeconomic status was found to be significantly associated with QOL scores, which was similar to other studies from India.(68) More adverse events (higher LAEP scores) were also associated with poor QOL, similar to other studies from India, Korea and China.(11,68,74) The severity of seizures was similarly strongly associated with poor QOL.(43) However in this study, the factors like increased frequency of seizures, duration of illness and number of medications, were not significantly associated with poor QOL, unlike other studies from India.

This could be due to the different settings for the studies. Most of the other studies were based in tertiary care centers or specialist clinics, where the patients with more severe conditions would be selectively seen as opposed to the current community based study.

The individual patient and his/her perceived quality of life, does not exist in a vacuum, but his/her social, economic environment, presence of other health conditions especially psychiatric conditions like depression and anxiety, and finally the presence of adverse effects of the treatment affect his/her health outcomes.

There are existing government schemes, which offer loans to start small businesses to economically backward individuals. The individuals with epilepsy should be made aware of such schemes and utilize them. Better education opportunities and skill training can increase the job options available to safer options like clerical jobs rather than daily wage jobs which expose the person to work site hazards like heights and moving equipment.

8 Conclusions

This study set out to examine the quality of life in persons with epilepsy, and the risk factors for poor quality of life using a cross-sectional, community based study. A total of 160 individuals with epilepsy were included in the study. The quality of life score had a mean value of 65.20 (SD = 16.37), thus implying that a majority of the individuals with epilepsy were satisfied with the quality of their lives.

In bivariate analysis, lower socioeconomic status, type of seizure, time since last episode, number of seizures in last six months, higher scores on seizure severity score, higher score on Liverpool adverse effects profile, anxiety and depression were significantly associated with poorer quality of life score.

In multivariate analysis, low socioeconomic status, presence of depression, higher scores on seizure severity score, higher score on Liverpool adverse effects profile continued to be significantly associated with poor quality of life.

Possible interventions can include regular screening for depression and anxiety among individuals with epilepsy and prompt management of the conditions through medications or behavior therapy, and use of occupational therapy to keep individuals occupied in wage earning activities. Another option to improve the financial condition of the families is through access to government schemes for microfinance.

9 Recommendations

There are many studies, which have looked at possible interventions for epilepsy from surgery to newer anti-epileptic drugs, behavioral intervention, and modification of co morbidities. As can be seen from the study findings, socioeconomic status, severity, presence of adverse effects and depression are some of the factors, which influence the quality of life. The interventions needed are also holistic and should include multiple approaches to improve control over the seizures and decrease the adverse effects of the medications.

The possible interventions can be divided into interventions to improve the control over epilepsy, to decrease the side effects of the medications, to improve the coping skills of individuals with epilepsy and better management of comorbidities.

Interventions to improve control over epilepsy can include changing medications to newer anti-epileptic medications, which have fewer side effects but cost is a major limitation. The State run Public Health System can play an important role in addressing this issue.

For individuals with intractable epilepsy, surgery is an option that if made available by the Government Health System, can be offered for patients. There are a few centers in India where epilepsy surgeries are carried out, out of which, six are government and 12 are private institutions. A referral system can be set up to systematically refer patients to the nearest treatment centres.(92–95)

More research is needed into other interventions like modification of diet to low carbohydrate diet, use of yoga and alternate systems of medicine (AYUSH) in improving seizure control and improving the quality of life.(73,96)

There is also a great need for further research in to interventions for occupational therapy, as socioeconomic status and occupation were factors that had influence on the quality of life.

To improve the coping skills of individuals and families, increased knowledge about the condition, formation of peer support groups and having specialist clinics can be potential interventions.(97,98)

The presence of depression and anxiety can complicate the management of epilepsy due to drug interactions as well as decreasing the quality of life. Regular screening for depression and anxiety among patients and prompt treatment of these conditions would also help improve the quality of life of individuals with epilepsy.

10 Limitations of the study

The study utilized pre-existing lists of individuals with epilepsy, which did not include the individuals who the health workers were unaware of. While every attempt was made to include an exhaustive list of possible factors that could affect the health related quality of life, some factors were still missed. There is a high level of stigma among patients with epilepsy, which could affect the disclosure of the condition to the health workers. Even among the participants of the study, the scores for social participation were lower than other components, which can be an indicator of felt stigma.

An attempt to contact all participants was made only once. All the participants were interviewed early in the morning or late in the evening. Even then some people who worked in shifts, and were out of town were missed. This could have introduced selection bias in the study. The revisited participants were smaller in proportion (20) out of which 5 were included. A better approach could have been re-visiting all the participants.

Volunteer bias, a form of selection bias, is also possible as the individuals who agreed to participate could have been different from those who did not respond. However in this study, none of the subjects visited, refused participation.

Recall bias is a possibility as individuals with a longer duration of disease, would not remember the details of the condition accurately.

The study was conducted in Tamil, which was not the primary language of the investigator and there a possibility of some details being lost in translation.

However this was addressed by making use of the health aides of the CHAD program to help in translating during the interviews.

12 Summary

Epilepsy is one of the commonest neurological conditions, with an estimated prevalence of 4-10/1000 globally. It contributed to 0.75% of the global burden of disease and led to the loss of 20.6 million disability adjusted life years (DALYs). The estimated prevalence of epilepsy in India is 5.36/1000, with a higher prevalence in rural than urban areas. In Vellore district a previous study had found a prevalence of 3.8/1000. According to WHO estimates there is a 70% treatment gap in the care provided to individuals with epilepsy. Individuals own perception of their position in life and society is reflected in the quality of life score. The health related quality of life includes health factors that both positively and negatively impact the quality of life. There is a lack of knowledge regarding the health related quality of life among individuals living with epilepsy at the community level and the factors associated with poor quality of life in a rural population. The protective as well as risk factors for the poor quality of life if known can help direct future research to formulate more effective strategies to help individuals and their families to cope with the disease thus improving their quality of life and decrease the burden on individuals, their families and the community. Individuals who have poor quality of life can be offered more support in terms of counseling or changes in medication.

The aim of this study was to assess the Health Related Quality Of Life (HRQOL) of persons living with epilepsy in Kaniyambadi block of Vellore district. The

objectives of this study were, to assess the Health Related Quality Of Life (HRQOL) of persons aged 18 years and above living with epilepsy residing in Kaniyambadi block, Vellore and to identify the risk factors associated with poor HRQOL in persons living with epilepsy residing in Kaniyambadi block, Vellore. This was a community based cross sectional study conducted from March 2016 to August 2016, in Kaniyambadi block of Vellore district, with a sample size of 160. The Individuals who were aged 18 years and above, identified as having seizure disorder or epilepsy from records maintained by Community Medicine department and living in Kaniyambadi block for at least 6 months were included in the study. Pregnant women, individual unavailable at the time of survey, or unable to comprehend the questionnaire were excluded.

Individuals who met the inclusion criteria, were visited at home accompanied by the health aide and were administered the study questionnaire. The study questionnaire consisted of the validated Tamil version of the Quality of life in epilepsy-31(QOLIE-31), socio-demographic, epilepsy related questions, seizure severity questionnaire, Liverpool adverse effects profile, generalized anxiety disorder-7 and patient health questionnaire-9.

In the study the overall mean score for quality of life was 65.2 with a standard deviation of 16.37. The domain with the lowest score was social function, with a mean score of 54.22. The domain with the highest score was medication effects, with a mean score of 91.96. The LAEP also had a low mean score of 29.6 out of a maximum possible score of 76. Other studies done in South India, including a study done in a hospital serving the population of the block in 2007, found that mean

QOL score was 61.49 (12.56) and 51.49 (12.31). Both of these studies used WHO-BREF to assess the quality of life.

The prevalence of depression among the respondents was 40.62%, and it was associated with poor quality of life. Similarly prevalence of anxiety disorders was 46.88% and it was associated with poor quality of life. Other factors that were significantly associated with poor QOL scores were socioeconomic status, adverse effects and seizure severity. On multivariate analysis all three along with depression continued to be significantly associated with poor quality of life. In other studies from south India, age greater than 30 years, being married, being less educated and female had poorer quality of life, while in a another community based study from south India participants who were single, had less schooling, not currently working, had lower per capita income, and had anxiety or depressive symptoms had poorer quality of life. Individuals with epilepsy should be routinely screened for depression and anxiety and offered treatment for the same. Social participation by people with epilepsy should be encouraged. People living with epilepsy can and should be trained to enable them to join the work force and contribute to their family and society.

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ANNEXTURE 1: Information Sheet And Consent Form (English)

Department of Community Medicine, CMC Vellore

Information sheet

Study title:

A study on health related quality of life among people living with epilepsy and the factors associated with poor quality of life in Kaniyambadi block,Vellore District.

Dear Participant,

Thank you for showing interest in this research work. Please read the following information and clarify your doubts before you decide to take part in this research.

Purpose of this research: The objective of the study is to understand the health related quality of life of people with epilepsy and the factors associated with poor quality of life. A chronic disease like epilepsy affects the life of people in many ways and can lead to problems in working and leading a healthy life. This study will help assess the presence and amount of decreased quality of life understand the factors for the same. which will help the to better prevent decrease in the quality of life and help improve it.

Who all can take part: This study is enrolling all the epilepsy patients from Kaniyambadi block [redacted] from September 2015 to March 2016. This study will enroll total of 160 patients.

Responsibilities of participant: If you accept to participate in the survey you are expected to answer a few questions regarding your personal details, disease related details, feelings regarding medications and illness.

Duration of participation: It will take about 20 to 30 minutes to complete all the questions.

Risks: There is no risk associated with participating in this study by answering the questions.

Benefits: The indirect benefits of participating in this study are, patient will receive an assessment of their health status. For those with depression and medication side-effects appropriate treatment will be given or medications will be changed if needed.

Compensation: By participating in this study there no unforeseen risk of injury is expected which require compensation.

Confidentiality: The information you provide would be kept confidential. For the research purpose your name will be deleted and no identification markers will be used when sharing information to the public or during publication of the research findings.

Payments: No direct payment is provided to the participant for participation in the study.

If you have read and understood the information provided above and are willing to participate in this study, please be aware that your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any point of time during study without any loss of service from hospital where you are currently on treatment.

If you have any further questions please contact, [redacted], principal investigator,

Department of Community Medicine

CMC Vellore.

[redacted]

Community Medicine Department,CMC Vellore
Informed Consent

Study Title: A study to assess the health related quality of life among people living with epilepsy and the factors associated with poor quality of life among them in Kaniyambadi block of Vellore District

Study Number: _____

Subject's name with initials: _____

Date of Birth / Age: _____

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I amfree to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the Sponsor – **Fluid Research fund CMC Vellore**, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from this study. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).[ ]

(v) I agree to take part in the above study.[ ]

Name:

Signature (or thumb impression):

Date: ____/____/_____

Name of witness:

Signature (or thumb impression of witness):

Date:____/____/_____

Investigator's signature:

ANNEXTURE 2: SURVEY QUESTIONNAIRE (ENGLISH)

A STUDY TO ASSESS THE QUALITY OF LIFE AMONG PEOPLE WITH EPILEPSY AND FACTORS AFFECTING THE QUALITY OF LIFE IN KANIYAMBADI BLOCK

PART 1 DEMOGRAPHY		DATE
	STUDY NUMBER	
	VILLAGE NAME	
	NAME	
	AGE	
	SEX	
	OCCUPATION	
	MARITAL STATUS	
	AVERAGE MONTHLY INCOME	
	EDUCATION IN COMPLETED YEARS	
	LITERACY	
	TYPE OF FAMILY	
	FAMILY SIZE(NO. OF FAMILY MEMBERS)	
	SOCIO-ECONOMIC SCORE TOTAL	

1. Education (head of the family)

	Score
Profession or Honors	7
Graduate or postgraduate	6
Intermediate or post high school diploma	5
High school certificate	4
Middle school certificate	3
Primary school certificate	2
Illiterate	1

2. Occupation (head of the family)

	Score
Profession	10
Semi-profession	6
Clerical, shop-owner, farmer	5
Skilled worker	4
Semi-skilled worker	3
Unskilled worker	2
Unemployed	1

3. Family income per month (mod.2012)

	Score
≥31,507	12
15,754-31,506	10
11,817-15,753	6
7,878 – 11,816	4
4727-7877	3
1590-4726	2
≤1589	1

PART 2 DISEASE SPECIFIC FACTORS		
	DURATION OF ILLNESS IN YEARS	
	AGE AT ONSET OF SEIZURE	
	FAMILY HISTORY OF SEIZURES	
	NUMBER OF ANTI EPILEPTIC MEDICATIONS	
	TYPE OF SEIZURE	
	ETIOLOGY	

	NUMBER OF SEIZURES OVER LAST SIX MONTHS							
	CO-MORBIDITIES IF ANY							
PART 3 SEIZURE SEVERITY QUESTIONNAIRE								
	BEFORE SEIZURES (most common type)							
	1.Did you have a warning (aura) BEFORE this type of seizure (smell, feeling, sensation, etc.) in the past one year?						NO	YES
	1A. If "yes", was the warning (aura) HELPFUL; for example, did it allow you to prepare for the seizure?	1 Very	2	3	4 Some what	5	6	7 No
	DURING SEIZURES							
	2. Did you have movements or actions DURING this type of seizure in the past 4 weeks (such as automatic movements, uncontrollable actions, falling, injury, tongue biting, wetting pants with urine, etc.)?						No	Yes
	A. If yes, how SEVERE (INTENSE) were the movements or actions overall?	1 No	2	3	4 Some what	5	6	7 very
	2B. How BOTHERSOME (interfere with your life) were the movements or actions overall?	1 No	2	3	4 Some what	5	6	7 very
	3. Did you have ONLY altered consciousness (blank-out) or sensations (no movements or actions) with this type of seizure in the past one year?						No	Yes
	3A. If yes, how BOTHERSOME (interfere with your life) were these periods of altered consciousness?	1 No	2	3	4 Some what	5	6	7 No
	AFTER SEIZURES							
	Did it take a while to recover (get back to normal) AFTER this type of seizure in the past one year						No	Yes
	5. Did you have Cognitive Effects (confusion, loss of memory or speech, walk or talk without purpose, etc.) AFTER seizures?						No	Yes
	5A. If yes, how OFTEN did you have Cognitive Effects AFTER seizures?	1 never	2	3	4 Some what	5	6	7 very
	5B. How SEVERE (INTENSE) were the Cognitive Effects AFTER seizures?	1 Very	2	3	4 Some what	5	6	7 No
	5C. How BOTHERSOME were the Cognitive Effects AFTER seizures?	1 Very	2	3	4 Some what	5	6	7 No
	6. Did you have Emotional Effects (depression, anxiety, anger, etc.) AFTER seizures?						No	Yes
	6A. If yes, how OFTEN did you have Emotional Effects AFTER seizures?	1 never	2	3	4 Some what	5	6	7 very
	6B. How SEVERE (INTENSE) were the Emotional Effects AFTER seizures?	1 No	2	3	4 Some what	5	6	7 No
	6C. How BOTHERSOME were the Emotional Effects AFTER seizures?	1 No	2	3	4 Some what	5	6	7 No
	7. Did you have Physical Effects (sleepy, tired, weak, sore muscles, headache) AFTER seizures?						No	Yes
	7A. If yes, how OFTEN did you have Physical Effects AFTER seizures?	1 never	2	3	4 Some	5	6	7 very

					what			
	7B. How SEVERE (INTENSE) were the Physical Effects AFTER seizures?	1 No	2	3	4 Some what	5	6	7 very
	7C. How BOTHERSOME were the Physical Effects AFTER seizures?	1 No	2	3	4 Some what	5	6	7 No
	OVERALL ASSESSMENT							
	8. How SEVERE (INTENSE) were your seizures overall in the past one year?	1 No	2	3	4 Some what	5	6	7 No
	9. How BOTHERSOME (interfere with your life) were your seizures overall in the past one year?	1 No	2	3	4 Some what	5	6	7 No
	10. What is most bothersome about your seizures overall (mark only one):	Warning (aura) before the seizure			Activities during the seizure		Recovery after the seizure	
	11. How have your seizures changed in severity or bothersomeness since changing seizure treatment?	-7	-6	-5	-4	-3	-2	-1	0
		7	6	5	4	3	2	1	

PART 4 LIVERPOOL ADVERSE EVENTS PROFILE				
Over a period of 6 months how many generalised tonic clonic seizures (grand mal seizures) do you have?				
Over a period of 6 months how many non-convulsive seizures (partial seizures, absences, petit mal) do you have?				
If known, please enter if your seizures are classified as being generalised or partial				
Please enter your medication including name and daily dose				
During the last four weeks have you had any of the problems listed below?	**Always or often a problem 4**	**Sometimes a problem 3**	**Rarely a problem 2**	**Never a problem 1**
a) unsteadiness				
b) tiredness				
c) restlessness				
d) feelings of anger or aggression to others				
e) nervousness and/or agitation				
f) headache				
g) hair loss				
h) problems with skin(eg acne, rash)				
i) double or blurred vision				
j) upset stomach				
k) difficulty in concentrating.				
l) trouble with mouth or gums				
m) shaky hands				
n) weight gain				
o) dizziness				
p) sleepiness				
q) depression				
r) memory problems				
s) disturbed sleep				
t) any other problem (please list in the space below and ring the appropriate number to indicate your response				
u				

v				
w				

PART 5 Generalised Anxiety disorder-7					
	Over the last 2 weeks, how often have you been bothered by the following problems?	**Not at all 0**	**Several days 1**	**More than half the days 2**	**Nearly every day 3**
	Feeling nervous, anxious or on edge				
	Not being able to stop or control worrying				
	Worrying too much about different things				
	Trouble relaxing				
	Being so restless that it is hard to sit still				
	Becoming easily annoyed or irritable				
	Feeling afraid as if something awful might happen				
	TOTAL SCORE				

PART 6 : PHQ-9				
How often in the last four weeks have you had	Not at all 0	Several days 1	More than half the days 2	Nearly every day 3
Little interest or pleasure in doing things				
Feeling down, depressed or hopeless				
Trouble falling or staying asleep or sleeping too much				
Feeing tired or having little energy				
Poor appetite or overeating				
Feeling bad about yourself or that you are a failure or have let yourself or your family down				
Trouble concentrating on things like reading newspapers or watching television				
Moving or speaking so slowly that other people could have noticed or moving around a lot more than usual being fidgety or restless				
Had thoughts that you would have been better off dead or hurting yourself				
Total				
If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?				

QUALITY OF LIFE IN EPILEPSY – PROBLEMS: QOLIE-31-P (*Version 2*)

Today's Date_____/ _____/ _____
mm dd yy

Name _____ Age: ___ ___ years

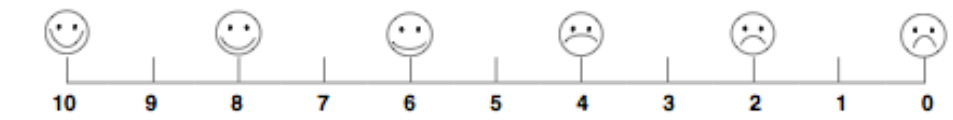
INSTRUCTIONS

The QOLIE-31-P is a survey of health-related quality of life for adults (18 years or older) with epilepsy. [Adolescents (ages 11-17 years) should complete the QOLIE-AD-48, designed for that age group.] This version differs from the original QOLIE-31 (version 1) in the addition of questions about how much distress you feel about problems and worries related to epilepsy. This questionnaire should be completed only by the person who has epilepsy (not a relative or friend) because no one else knows how YOU feel.

There are 38 questions about your health and daily activities. Answer every question by circling the appropriate number (1, 2, 3...). If you are unsure about how to answer a question, please give the best answer you can and write a comment or explanation on the side of the page. These notes may be useful if you discuss the QOLIE-31-P with your doctor. Completing the QOLIE-31-P before and after treatment changes may help you and your doctor understand how the changes have affected your life.

This copy of the QOLIE-31-P is provided by www.epilepsy.com, your source for epilepsy information, and the QOLIE Development Group. We wish you success in living your life with epilepsy!

1. Overall, how would you rate your quality of life?
(Circle one number on the scale below)



Part A.

These questions are about how you have been FEELING during the past 4 weeks. For each question, please indicate the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks…

(Circle one number on each line)

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
2. Did you feel full of pep?	1	2	3	4	5	6
3. Did you have a lot of energy?	1	2	3	4	5	6
4. Did you feel worn out?	1	2	3	4	5	6
5. Did you feel tired?	1	2	3	4	5	6

*Reviewing only questions in **Part A**, consider the overall impact of these issues on your life **in the past 4 weeks**.*

(Circle one number)

	Not at all	Somewhat	Moderately	A lot	Very much
6. How much do the above problems and worries about energy **distress** you overall?	1	2	3	4	5

Part B.

These questions are about how you have been FEELING during the past 4 weeks. For each question, please indicate the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks…
(Circle one number on each line)

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
7. Have you been a very nervous person?	1	2	3	4	5	6
8. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
9. Have you felt calm and peaceful?	1	2	3	4	5	6
10. Have you felt downhearted and blue?	1	2	3	4	5	6
11. Have you been a happy person?	1	2	3	4	5	6

*Reviewing only questions in **Part B**, consider the overall impact of these issues on your life **in the past 4 weeks.***

(Circle one number)

	Not at all	Somewhat	Moderately	A lot	Very much
12. How much do the above problems and worries about <u>emotions</u> **distress** you overall?	1	2	3	4	5

Part C.

The following questions are about how you FEEL and about problems you may have with daily ACTIVITIES during the past 4 weeks. For each question, please indicate the one answer that comes closest to the way you have been feeling.

The following question asks about how you FEEL and how things have been going for you.

How much of the time during the past 4 weeks…

(Circle one number)

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
13. Has your health limited your social activities (such as visiting with friends or close relatives)?	1	2	3	4	5	6

The following questions ask about problems you may have with certain ACTIVITIES.

How much of the time during the past 4 weeks your epilepsy or antiepileptic medication has caused trouble with…

(Circle one number on each line)

	A great deal	A lot	Somewhat	Only a little	Not at all
14. Leisure activities (such as hobbies, going out)	1	2	3	4	5
15. Driving (or transportation)	1	2	3	4	5

	Not at all bothersome				Extremely bothersome
16. How much do your work limitations bother you?	1	2	3	4	5
17. How much do your social limitations bother you?	1	2	3	4	5

*Reviewing only questions in **Part C**, consider the overall impact of these issues on your life **in the past 4 weeks**.*

(Circle one number)

	Not at all	Somewhat	Moderately	A lot	Very much
18. How much do the above problems and worries about daily activities **distress** you overall?	1	2	3	4	5

Part D.

These questions are about thinking, reading, concentrating and memory problems you may have had during the past 4 weeks. For each question, please indicate the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks…

(Circle one number)	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
19. Did you have difficulty reasoning and solving problems (such as making plans, making decisions, learning new things)?	1	2	3	4	5	6

	Yes, a great deal	Yes, somewhat	Only A little	No, not at all
20. In the past 4 weeks, have you had any trouble with your memory?	1	2	3	4

In the past 4 weeks, how often have you had…

(Circle one number on each line)	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
21. Trouble remembering things people tell you?	1	2	3	4	5	6
22. Trouble concentrating on reading?	1	2	3	4	5	6
23. Trouble concentrating on doing one thing at a time?	1	2	3	4	5	6

	Not at all bothersome				Extremely bothersome
24. How much do your memory difficulties bother you?	1	2	3	4	5

*Reviewing only questions in **Part D**, consider the overall impact of these issues on your life **in the past 4 weeks**.*

(Circle one number)

	Not at all	Somewhat	Moderately	A lot	Very much
25. How much do the above problems and worries about mental function **distress** you overall?	1	2	3	4	5

Part E.

These questions are about problems you may have related to your epilepsy or antiepileptic medication.

During the past 4 weeks…

(Circle one number on each line)

	Not at all bothersome				Extremely bothersome
26. How much do physical effects of antiepileptic medication bother you?	1	2	3	4	5
27. How much do mental effects of antiepileptic medication bother you?	1	2	3	4	5

	Very worried	Somewhat worried	Not very worried	Not worried at all
28. How worried are you that medications you are taking will be bad for you if taken for a long time?	1	2	3	4

*Reviewing only questions in **Part E**, consider the overall impact of these issues on your life **in the past 4 weeks**.*

(Circle one number)

	Not at all	Somewhat	Moderately	A lot	Very much
29. How much do the above problems and worries about the effects of medication **distress** you overall?	1	2	3	4	5

Part F.

These questions are about how you FEEL about your seizures during the past 4 weeks. For each question, please indicate the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks…

(Circle one number)	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
30. Have you worried about having another seizure?	1	2	3	4	5	6

	Very fearful	Somewhat fearful	Not very fearful	Not fearful at all
31. How fearful are you of having a seizure during the next month?	1	2	3	4

	Worry a lot	Occasionally worry	Don't worry at all
32. Do you worry about hurting yourself during a seizure?	1	2	3

	Very worried	Somewhat worried	Not very worried	Not at all worried
33. How worried are you about embarrassment or other social problems resulting from having a seizure during the next month?	1	2	3	4

	Not at all bothersome				Extremely bothersome
34. How much do your seizures bother you?	1	2	3	4	5

*Reviewing only questions in **Part F**, consider the overall impact of these issues on your life **in the past 4 weeks**.*

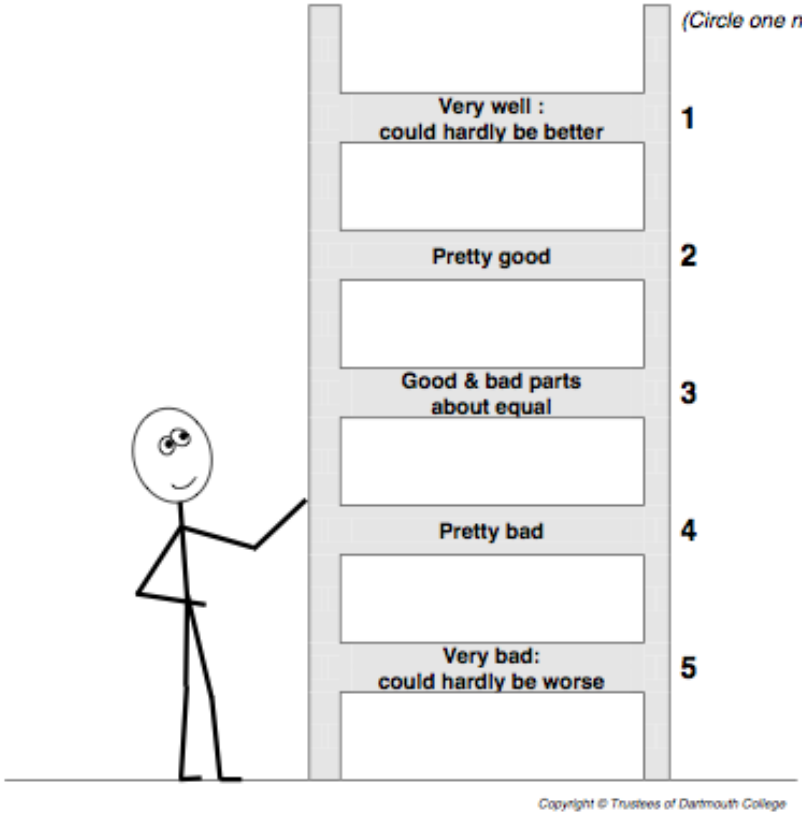
(Circle one number)

	Not at all	Somewhat	Moderately	A lot	Very much
35. How much do the above problems and worries about seizures **distress** you overall?	1	2	3	4	5

Part G.

The following question asks about how you FEEL about your overall quality of life. Please indicate the one answer that comes closest to the way you have been feeling.

36. How has the **QUALITY OF YOUR LIFE** been during the **past 4 weeks** (that is, how have things been going for you)?



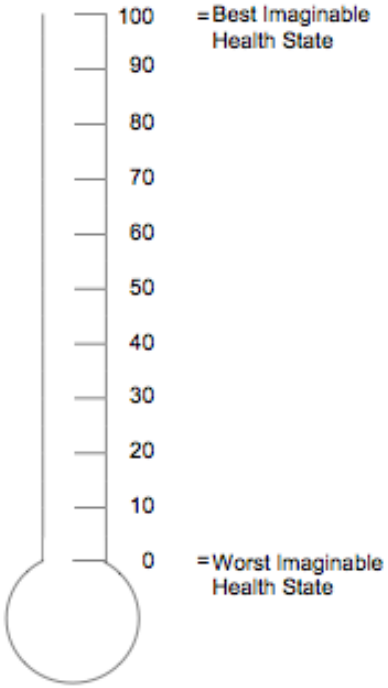
*Reviewing only questions 1 and 36 in **Part G** (on page 1 and this page), consider the overall impact of your quality of life **in the past 4 weeks**.*

(Circle one number)

	Not at all	Somewhat	Moderately	A lot	Very much
37. How much does the state of your quality of life **distress** you overall?	1	2	3	4	5

Part H.

38. How good or bad do you think your HEALTH is?
On the scale below, the best imaginable state of health is 100 and the worst imaginable state is zero (0). Please indicate how you feel about your health by circling one number on the scale. **Please consider your epilepsy as part of your health when you answer this question.**



Part I.

*Considering **ALL** the questions you have answered, please **indicate the areas** related to your epilepsy that are most **IMPORTANT** to you **NOW.***

39. Number the following topics from '1' to '7', with '1' corresponding to the very most important topic and '7' to the least important one. Please use each number only once.

___ **A.** Energy (tiredness)

___ **B.** Emotions (mood)

___ **C.** Daily activities (work, driving, social)

___ **D.** Mental activity (thinking, concentrating, memory)

___ **E.** Medication effects (physical, mental)

___ **F.** Seizure worry (impact of seizures)

___ **G.** Overall quality of life

ANNEXURES 3-INFORMATION SHEET AND CONSENT FORM (TAMIL)

ஆய்வுக்கான தகவல் அறிக்கை

1. **ஆய்வின்தலைப்பு:**

வேலூர் மாவட்டம் கன்னியம்பாடி பகுதியில் உள்ள வலிப்பு நோயால் பாதிக்கப்பட்டவர்களின் சுகாதாரம் சார்ந்த வாழ்க்கை தரம் மற்றும் வாழ்கை தரத்தை பாதிக்கும் காரணிகளை அறிதல் குறித்த ஆறாய்ச்சி

[redacted] வேலூர் -2

நீங்கள் இந்த ஆய்வில் பங்கேற்க அழைக்கப்படுகிறீர்கள். இந்த ஆய்வு எதற்காக நடத்தப்படுகிறது,எப்படி நடத்தப்படும் போன்ற தகவல்கள் உங்களுக்கு விளக்கப்படும். இந்தஆய்வினைக் குறித்த முழுமையான தகவல்கள் இந்த தகவல் அறிக்கையில் உள்ளது. இந்த தகவல் அறிக்கையின் நகல் உங்களுக்குக் கொடுக்கப்படும். இந்த ஆய்வினைக் குறித்த ஏதேனும் சந்தேகம் இருந்தால் ஆய்வாளரிடம் கேற்பதற்கு உங்களுக்கு முழு உரிமை உண்டு.

ஆராய்ச்சியின் நோக்கம்:

வலிப்பு நோயால் பாதிக்கப்பட்டவர்களின் சுகாதாரம் சார்ந்த வாழ்க்கை தரம் மற்றும் வாழ்கை தரத்தை பாதிக்கும் காரணிகளை அறிய இந்த ஆறாய்ச்சி நடத்தபடுகிறது.வலிப்பு நோயால் மருத்துவம் சார்ந்த மற்றும் அன்றாட செயல்களிலும் பல இன்னல்களை நோயாளிகள் சந்தித்து வருகின்றனர்.இந்த ஆறாய்ச்சி மூலம் எந்த அளவுக்கு நோயாளிகளின் வாழ்கை தரம் பாதிகபட்டுள்ளது அதற்கு என்ன கரணம் என அறிய முடியும். இதன் மூலம் அக்காரணங்களை அறிந்து தவிர்க்க இயலும்.

யார் பங்கேற்கலாம்?

இந்த ஆய்வானது கணியம்பாடி வட்டாரத்தில் உள்ள வலிப்பு நோயால் பாதிக்கப்பட்டு [redacted] கலந்துகொள்ளலாம். செப்டம்பர் 2015 முதல் மார்ச் 2016 வரை 160 நோயாளிகள் பங்கேற்கலாம்.

ஆய்வுஎப்படிநடத்தப்படும்?

இந்த ஆய்வில் பங்கேற்க சம்மதித்தால் உங்களை பற்றியும் உங்கள் நோய் குறித்தும் சில கேள்விகளுக்கு பதில் அளிக்க வேண்டி இருக்கும். சுமார் 20 முதல் 30 நிமிடம் வரை இதற்கு ஆகலாம்.

ஆய்வில்பங்கேற்பதினால் பாதிப்புகள்எதுவும்ஏற்படுமா?

ஆய்வில் பங்கேற்பதினால் வேறு எந்தவிதமான பக்கவிளைவுகளும் ஏற்படாது.

இழப்பீடு

எந்த இழப்பீடும் வழங்கப்படமாட்டாது.

ஆய்வில் பங்கேற்பதினால் என்ன பயன் கிடைக்கும்?

இந்த ஆய்வில் பங்கேற்பதன் மூலம் ஏற்படும் மறைமுக பயன் தங்களின் சுகாதார நிலை குறித்து அறிதல் ஆகும். மாத்திரைகளின் பாதிப்போ அல்ல மன அழுத்தம் இருப்பது கண்டுபுடிக்க பட்டாள் அதற்கான வைத்தியம் வழங்க படும்.

ஆய்வில் பங்கேற்கவில்லை என்றால் என்ன நடக்கும்?

இந்த ஆய்வில் பங்கேற்காமல் போனால் எந்த இழப்பும் உங்களுக்கு ஏற்படாது. சாட் / கிறிஸ்துவ மருத்துவக் கல்லூரி மருத்துவமனையில் உங்களுக்கு வழங்கப்படும் சிகிச்சையில் எந்த குறைவும் ஏற்படாது .

ஆய்விலிருந்து இடையில் விலகிக்கொள்ள இயலுமா?

இந்த ஆய்வில் இருந்து விலக விரும்பினால் ஆய்வாளரிடம் தெரிவித்துவிட்டு எப்போது வேண்டுமானாலும் நீங்கள் விலகிக்கொள்ளலாம் .

ரகசியக்காப்பு

இந்த ஆய்விற்காக சேகரிக்கப்படும் தகவல்கள் எல்லாம் பாதுகாப்பாக வைக்கப்படும் .இந்த ஆய்வின் முடிவுகள் கிறிஸ்துவ மருத்துவக் கல்லூரி மற்றும் இந்திய அரசோடு மட்டும் பகிர்ந்து கொள்ளப்படும்.

கேள்விகள் இருந்தால்

இந்த ஆய்வு பற்றி வேறு ஏதேனும் கேள்விகள் இருந்தால் [redacted]

ஒப்புதல்படிவம்

1.ஆய்வின்தலைப்பு:

வேலூர் மாவட்டம் கன்னியம்பாடி பகுதியில் உள்ள வலிப்பு நோயால் பாதிக்கப்பட்டவர்களின் சுகாதாரம் சார்ந்த வாழ்க்கை தரம் மற்றும் வாழ்கை தரத்தை பாதிக்கும் காரணிகளை அறிதல் குறித்த ஆராய்ச்சி

2.ஆய்வாளரின்பெயர்&தொடர்பு விபரங்கள்

வேலூர் -2

ஆய்வில் பங்கேற்பவரின் பெயர் :

வயது: ஊர்:

வலிப்பு நோயால் பாதிக்கப்பட்டவர்களின் சுகாதாரம் சார்ந்த வாழ்க்கை தரம் மற்றும் வாழ்கை தரத்தை பாதிக்கும் காரணிகளை அறிய இந்த ஆராய்ச்சி நடத்தபடுகிறது என்பதைஅறிந்து கொண்டேன்

இந்தஆய்வில் பங்கேற்பதினால் சிலகேள்விகளுக்கு நான் பதிலளிக்க வேண்டி இருக்கும் எனத் தெரிந்துகொண்டேன் . இந்த ஆய்வில் பங்கேற்காமல் போனால் எந்த இழப்பும் எனக்குஏற்படாது. சாட் மருத்துவமனை / கிறிஸ்துவ மருத்துவக்கல்லூரி மருத்துவமனையில் எங்களுக்கு வழங்கப்படும் சிகிச்சையில் எந்தகுறைவும்ஏற்படாது.இதனால் எந்தவிதமான பக்க விளைவுகளும் ஏற்படாது. இந்தஆய்வில் பங்கேற்க எந்தவிதமான வெகுமதிகளோ /பணமோ எனக்கு வழங்கப்படாது. இந்த ஆய்விற்காக சேகரிக்கப்படும் தகவல்கள் எல்லாம் பாதுகாப்பாக வைக்கப்படும். முன்னதாக தகவல் தெரிவித்து விட்டு எப்போது வேண்டுமானாலும் நான் விலகிக்கொள்ளலாம் .இந்தஆய்வின் முடிவுகள் கிறிஸ்துவ மருத்துவக்கல்லூரி மற்றும் இந்தியஅரசோடு மட்டும் பகிர்ந்து கொள்ளப்படும் போன்ற தகவல்களைத் தெரிந்துகொண்டேன் .

1. தகவல்அறிக்கையில் கொடுக்கப்பட்ட விவரங்களை எனது சொந்தமொழியில் வாசித்து /கேட்டுத் தெரிந்து/ புரிந்து கொண்டேன். கேள்விகள் கேட்கவும் எனக்கு வாய்ப்புகள் கொடுக்கப்பட்டன .

2.இந்தஆய்வில் சேரும் என்னுடைய முடிவு தன்னிச்சையானது .எந்த வற்புறுத்தலும் இல்லை. முன்னதாக தகவல் தெரிவித்து விட்டு எப்போது வேண்டுமானாலும், எந்தகாரணமும் தெரிவிக்காமல் நான் விலகிக் கொள்ளலாம் என்பதையும் அறிந்துகொண்டேன்.

3.இந்தஆய்விற்காக சேகரிக்கப்படும் தகவல்களை ஆய்வாளர், கிறிஸ்துவமருத்துவக்கல்லூரி மற்றும்ஆய்வுக்குழு எனதுசம்மதம் இல்லாமலே பிற ஆய்வுகளுக்கும் பயன்படுத்திக் கொள்ள முடியும் என அறிந்திருக்கிறேன் .இந்த தகவல்களை எதிர்கால ஆய்வுகளுக்குப் பயன்படுத்திக் கொள்ள சம்மதிக்கிறேன்

4.இந்தஆய்வில்பங்கேற்கமுழுமனதுடன்சம்மதிக்கிறேன்.

_____ _____ _____

பங்கேற்பாளர் பெயர்	பங்கேற்பாளர் கையெழுத்து	தேதி
_____	_____	_____
சாட்சி பெயர்	சாட்சி கையெழுத்து	தேதி
_____	_____	_____
ஆய்வாளர் பெயர்	ஆய்வாளர் கையெழுத்து	தேதி

ANNEXURE 4 - SURVEY INTRUMENT QUESTIONNAIRE (TAMIL)

கணியம்பாடி வடாரத்தில் வாழும் மக்களிடம் இழுப்பு நோயினால் பாதித்தவர்களை கண்டறிந்து வலிப்பு நோய் மற்றும் அதனால் வரும் பிரச்சனைகளைக் குறித்தான ஒரு ஆய்வு

பகுதி 1 பொது விபரங்கள்		தேதி							
	படிவ எண்								
	கிராம எண்								
	பெயர்								
	வயது								
	பாலினம்	ஆண்/ பெண்/பிற							
	தொழில்								
	திருமணமானவரா	ஆம்/இல்லை							
	மாத ச் சம்பளம் தோராயமாக								
	படிப்பு								
	எத்தனை வருட படிப்பு								
	எத்தகைய குடும்பம்								
	குடும்பத்தில்உள்ள நபர்கள்								
	சமூகப் பொருளாதார நிலை								
பகுதி 2 வலிப்பு நோயைப் பற்றி									
	ஏத்தனை வருடங்களாக உள்ளது								
	ஏப்போது தொடங்கியது								
	குடும்பத்தில் யாருக்கும் உள்ளதா								
	ஏந்த மாதிரி மருந்துகள் கொடுக்கப்பட்டது								
	ஏந்த வகையான வலிப்பு								
	ஏதனால் வந்தது								
	கடைசி ஆறு மாதங்களுக்குள் எத்தனை தடவை வலிப்பு வந்தது								
	ஏந்த வகையான தன்மையை உடையது								
பகுதி 3 வலிப்பு தன்மைப் பற்றிய கேள்விகள்									
	வலிப்பு நோய்க்கு முன்பு (சாதாரணமான வகை)								
	1. கடந்த 4 வாரங்களுக்குள் வலிப்பு வருவதற்கு முன்பு கீழ்க்கண்ட அறிகுறிகள் ஏதேனும் வந்ததா? (வாசனை உணர்வு, வேறு ஏதாவது உணர்ச்சிகள்)							ஆம்	இல்லை
	1 .அ)ஆம் என்றால் எவ்விதமாக அது உபயோகமாக உள்ளது? உதாரணம்: வலிப்பு நோய்க்கு உங்களை த் தயார் படுத்துகிறதா?	1 ரொம்ப	2	3	4 ஒரளவுக்கு	5	6	7 இல்லை	
	வலிப்பின் போது								
	2. கடந்த 4 வாரங்களுக்குள் கீழ்க்கண்ட அறிகுறிகள்/ செயல்கள் ஏதேனும் வந்ததா? (அதாவது தன்னைப் போல செயல்கள், தடுக்கமுடியாத செயல்கள், கீழே விழுந்து அடிபடுதல், நாக்கைக் கடித்தல், தன்னறிவின்றி சிறுநீர் கழித்தல் போன்றவை)							இல்லை	ஆம்
	அ)ஆம் என்றால் அது எந்த அளவிற்கு பாதிப்பு இருக்கும்?	1 இல்லை	2	3	4 ஒரளவுக்கு	5	6	7 ரொம்ப	
	ஆ இந்த வலிப்பு நோய் உங்கள் தனிப்பட்ட வாழ்க்கையை எவ்விதத்தில் பாதிக்கின்றது?	1 இல்லை	2	3	4 ஒரளவுக்கு	5	6	7 ரொம்ப	
	3. கடந்த 4 வாரங்களில் வலிப்பு நோய் வரும் போது எப்போதாவது மயக்கமாகவோ,							இல்லை	ஆம்

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Department of Community Medicine, CMC Vellore

	தன்னறிவின்றி) அல்லது செயல்பட முடியாமல் பாதிக்கப்பட்டீர்களா?						ஐ	
	அ. ஆம் என்றால் அது எந்த அளவிற்கு உங்கள் தனிப்பட்ட வாழ்க்கையை எவ்விதத்தில் பாதிக்கின்றது	1 இல்லை	2	3	4 ஓரளவுக்கு	5	6	7 ரொம்ப
	வலிப்பு நோய் வந்த பிறகு							
	கடந்த 4 வாரங்களில் வலிப்பு நோய் வந்த பிறகு நீங்கள் பழைய நிலையை அடைவதற்கு சிறிது நேரம் எடுத்தா?						இல்லை	ஆம்
	5 வலிப்பு நோய் வந்த கீழ்க்கண்ட பக்க விளைவுகள் ஏதேனும் வந்ததா (அதாவது குழப்பம், ஞாபகமின்மை, பேசமுடியாமை , காரணமில்லாமல் நடக்கவோ பேசவோ செய்தல்)						இல்லை	ஆம்
	அ. ஆம் என்றால் வலிப்பு நோய் வந்த பிறகு பக்க விளைவுகளால் அடிக்கடி பாதிக்கப்படுவீர்களா?	1 இல்லை	2	3	4 ஓரளவுக்கு	5	6	7 ரொம்ப
	ஆ. வலிப்பு நோய் வந்த பிறகு எந்த அளவிற்கு பாதிப்பு இருக்கும்?	1 இல்லை	2	3	4 ஓரளவுக்கு	5	6	7 ரொம்ப
	இ. வலிப்பு நோய் வந்த பிறகு வரும் பக்க விளைவு கள் உங்களை அதிகம் பாதிக்கினறதா?	1 இல்லை	2	3	4 ஓரளவுக்கு	5	6	7 ரொம்ப
	6. வலிப்பு வந்த பிறகு உங்களுக்கு கீழ்க்கண்டக் உணர்ச்சி கள் உள்ளதா? (கோபம், சோர்வுகள், எதிர்பார்ப்பு போன்றவை)						இல்லை	ஆம்
	அ. ஆம் என்றால் வலிப்பு வந்த பிறகு உங்களுடைய உணர்வுகள் எந்தளவுக்கு உள்ளது?	1 இல்லை	2	3	4 ஓரளவுக்கு	5	6	7 ரொம்ப
	ஆ. வலிப்பு வந்த பிறகு நீங்கள் எந்தளவிற்கு பாதிக்கப்பட்டீர்கள்	1 இல்லை	2	3	4 ஓரளவுக்கு	5	6	7 ரொம்ப
	இ. வலிப்பு வந்த பிறகு உங்களுடைய உணர்வுகள் பாதிக்கப் பட்டுள்ளதா?	1 இல்லை	2	3	4 ஓரளவுக்கு	5	6	7 ரொம்ப
	7. வலிப்பு வந்த பிறகு உங்களுக்கு தூக்கம், சோர்வு, தலைவலி, நரம்பு தளர்ச்சி போன்ற பிரச்சினைகள் ஏதேனும் உள்ளதா?						இல்லை	ஆம்
	அ ஆம், என்றால் வலிப்பு வந்த பிறகு சீர் விளைவுகளினால் அடிக்கடி அவதிப்படுவீர்களா?	1 இல்லை	2	3	4 ஓரளவுக்கு	5	6	7 ரொம்ப
	ஆ. வலிப்பு வந்த பிறகு நீங்கள் மோசமாக பாதிக்கப்பட்டீர்களா?	1 இல்லை	2	3	4 ஓரளவுக்கு	5	6	7 ரொம்ப
	இ. வலிப்பு வந்த பிறகு அது உங்களை எந்த அளவிற்கு பாதிப்பு அடைய செய்திருக்கின்றது?	1 இல்லை	2	3	4 ஓரளவுக்கு	5	6	7 ரொம்ப
	மொத்த மதிப்பீடுகள்							
	8. கடந்த நான்கு வாரங்களில் இந்த வலிப்பு வந்த பிறகு நீங்கள் எந்த அளவிற்கு மோசமாக அவதிக்குள்ளானீர்கள்?	1 இல்லை	2	3	4 ஓரளவுக்கு	5	6	7 ரொம்ப
	9. கடந்த நான்கு வாரங்களில் இந்த வலிப்பு வந்த பிறகு உங்கள் வாழ்க்கை எந்த அளவிந்து பாதிக்கப்பட்டுள்ளது?	1 இல்லை	2	3	4 ஓரளவுக்கு	5	6	7 ரொம்ப
	10. வலிப்பு வரும் பொழுது எது உங்களை அதிகமாக பாதிக்கின்றது? (ஒன்றை மட்டும் குறிக்கவும்):	வலிப்பு வருவதற்கு முன்பாக வரும் எச்சரிப்பு			வலிப்பின் போது இருக்கும் அறிகுறிகள்		வலிப்பு வந்த பின்பு பழைய நிலையை	

									அடையும் போது
	11. சிகிச்சை எடுத்தப் பின்பு நோயின் தாக்கத்தில் பக்க விளைவுகளில் ஏதாவது மாற்றம் உள்ளதா?	-7	-6	-5	-4	-3	-2	-1	0
		7	6	5	4	3	2	1	

பகுதி 4 லிவெர்பூல் பக்க விளைவுகள் தொடர்பான கேள்விகள்				
கடந்த 6 மாதங்களில் உங்களுக்கு வந்த இந்த வலிப்பு நோயானது இரண்டு கைகள் மற்றும் கால் களை ஒருசேரத் தாக்கியதா?				
கடந்த 6 மாதங்களில் உங்களுக்கு வந்த இந்த வலிப்பு நோயானது உங்கள் உடலின் ஒரு பகுதியை மட்டும் தாக்கியதா? (ஒரே பக்கமாக வலிப்பு , நினைவின்மை , மயக்கம்)				
உங்களுக்குக் கொடுக்கப்படும் மருந்து மாத்திரையைப் பற்றிய விவரங்களும் மற்றும் எடுத்துக் கொள்ளும் முறையும்				
கீழே கொடுக்கப்பட்டுள்ள பிரச்சனைகள் கடந்த 4 வாரங்களில் உங்களுக்கு இருந்ததா?	ஏப்போதும் அல்லது அடிக்கடி 4	சில நேரங்களில் 3	ஏப்போதாவது 2	ஒன்றுமில்லை 1
1) தள்ளாடுதல்				
2) சோர்வு				
3) அமைதியின்மை				
4) பிறர் மேல் கோபப் படுதல்				
5) படபடப்பு				
6) தலைவலி				
7) முடி கொட்டுதல்				
8) தோல் பிரச்சனை (அரிப்பு)				
9) தெளிவற்ற பார்வை அல்லது இரண்டு இரண்டாகத் தெரிதல்				
10) வயிற்றுக் கோளாறு				
11) கவனம் குறைதல்				
12) வாய் மற்றும் ஈறு பிரச்சனைகள				
13) கை நடுக்கம்				
14) எடை கூடுதல்				
15) மயக்கம்				
16) தூக்கமின்மை				
17) மனச் சோர்வு				
18) ஞாபகப் பிரச்சனை				
19) சரியான தூக்கமின்மை				
20) வேறு ஏதாவது பிரச்சனைகள் (பிரச்சனைகள் இருப்பின் பட்டியல் இடவும்)				

GAD-7

கடந்த 2 வாரங்களில், பின்வரும் பிரச்சனைகளால் நீங்கள் எவ்வளவு அடிக்கடி தொந்தரவுக்கு ஆளாகியிருக்கிறீர்கள்? *(உங்கள் பதிலைக் குறிப்பிட "✓" பயன்படுத்துங்கள்)*	இல்லவே இல்லை	பல நாட்களுக்கு	பாதிக்கு மேற்பட்ட நாட்களில்	அநேகமாக ஒவ்வொரு நாளும்
1. பதற்றமாக, மனவிசாரமாக அல்லது மிகவும் மன அழுத்தமாக உணர்தல்	0	1	2	3
2. கவலைப்படுவதை நிறுத்தவோ அல்லது கட்டுப்படுத்தவோ இயலாமை	0	1	2	3
3. வெவ்வேறு விஷயங்கள் பற்றி மிக அதிகமாகக் கவலைப்படுதல்	0	1	2	3
4. ஓய்வாக இருப்பதில் சிரமம்	0	1	2	3
5. அசையாமல் அமர்ந்திருக்க முடியாத அளவிற்கு இருப்புக்கொள்ளாமல் இருத்தல்	0	1	2	3
6. எளிதில் கோபமடைதல் அல்லது சிடுசிடுத்தல்	0	1	2	3
7. பயங்கரமாக எதேனும் நடந்துவிடுமோ என்று பயப்படுதல்	0	1	2	3

(For office coding: Total Score T____ = ____ + ____ + ____ + ____)

நோயாளியின் ஆரோக்கியம் தொடர்பான வினாப்பட்டியல் – 9
(PHQ-9)

கடந்த 2 வாரங்களில், பின்வரும் ஏதேனும் பிரச்சனைகளால் நீங்கள் எவ்வளவு அடிக்கடி தொந்தரவுக்கு ஆளாகியிருக்கிறீர்கள்? *(உங்கள் பதிலைக் குறிப்பிட "✓" பயன்படுத்துங்கள்)*	இல்லவே இல்லை	பல நாட்களுக்கு	பாதிக்கு மேற்பட்ட நாட்களில	அநேகமாக ஒவ்வொரு நாளும்
1. செயல்களை செய்வதில் சிறிதளவே ஆர்வம் அல்லது இன்பம்	0	1	2	3
2. உற்சாகமில்லாமல் இருந்தல், மனச்சோர்வு அடைதல், அல்லது நம்பிக்கை இல்லாதிருத்தல்	0	1	2	3
3. தூங்க முற்பட அல்லது தூக்கத்தில் இருக்க சிக்கல், அல்லது அதிக நேரம் தூங்குதல்	0	1	2	3
4. சோர்வாக உணர்தல் அல்லது சிறிதளவே சக்தி இருப்பதாக உணர்தல்	0	1	2	3
5. குறைந்த பசி உணர்வு அல்லது அதிகமாக உண்ணுதல்	0	1	2	3
6. உங்களை பற்றி நீங்களே மோசமாக உணர்தல் — அல்லது நீங்கள் தோல்வியை தழுவியதாக உணர்தல் அல்லது உங்களையோ அல்லது உங்கள் குடும்பத்தையோ விட்டுக் கொடுத்ததாக உணர்தல்.	0	1	2	3
7. விஷயங்களில் கவனம் செலுத்துவதில் சிரமம், செய்தித்தாள் படிப்பது, தொலைக்காட்சி பார்ப்பது போன்ற விஷயங்களைப் போல.	0	1	2	3
8. மிகவும் மெதுவாக பேசுவதாலும், நடப்பதாலும் மற்றவர்கள் உங்களை கவனித்திருக்க கூடுமா? அல்லது அதற்கு நேர்மாறாக — மிகவும் அமைதியற்று இருப்பதாலும் அல்லது மிகவும் நிலை கொள்ளாதிருப்பதாலும், நீங்கள் வழக்கத்திற்கு மாறாக அதிகமாக அங்கும் இங்குமாக சென்று வருகிறீர்கள்	0	1	2	3
9. இறந்து விடுவதே மேல் என்ற சிந்தனை அல்லது உங்களை நீங்களாகவே ஏதாவது ஒரு வகையில் வேதனைக்குள்ளாக்கிக் கொள்ள வேண்டும் என்ற சிந்தனைகள்	0	1	2	3

FOR OFFICE CODING 0 + _____ + _____ + _____

=Total Score: _____

நீங்கள் ஏதேனும் ஒரு பிரச்சனைக்கு அடையாள குறியிட்டிருந்தால், அந்த பிரச்சனைகள், உங்கள் வேலையை செய்யவிடாமல் இருப்பதிலும், தங்கள் குடும்பத்தை பார்த்துக்கொள்ள விடாமல் இருப்பதிலும், மற்றவர்களுடன் பழக விடாமல் இருப்பதிலும், எந்த அளவிற்கு கடினமானதாக அமைந்தன ?

கடினமாகவே இல்லை	ஓரளவுக்கு கடினம்	மிகவும் கடினம்	மிக மிக கடினம்
☐	☐	☐	☐

வாழ்க்கைத் தரம் பற்றிய ஆய்வுக் குறிப்பு

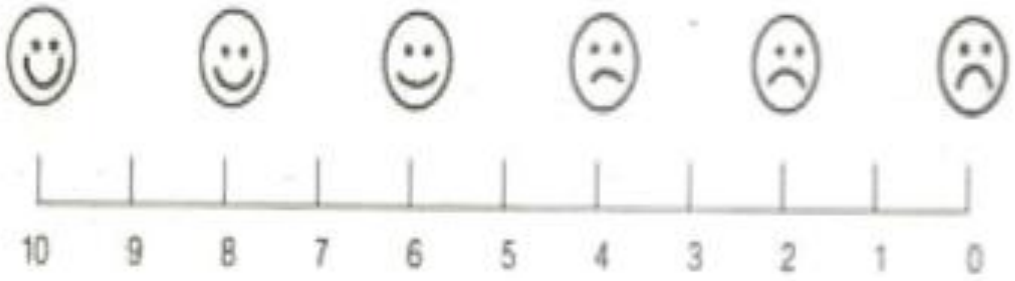
இந்த ஆய்வுக்குறிப்பு உங்களது ஆரோக்கியத்தையும், அன்றாட செயல்பாடுகளையும் தெரிந்து கொள்ள சேகரிக்கப்படுகிறது.

தேதி :

அடையாள எண். :

புறநோயாளி எண். :

1. 0 முதல் 10 வரையுள்ள அளவு கோளில் உங்களின் முழு வாழ்க்கைத் தரத்தை எந்த அளவில் மதிப்பிடுகிறீர்கள்?



சிறந்த சாத்தியமுள்ள வாழ்க்கைத் தரம் / ஆரோக்கியம் (என்னால் என்னுடைய அன்றாட வேலைகளை செய்து கொள்ள முடியும்)

மிகவும் மோசமான வாழ்க்கைத்தரம் / ஆரோக்கியம் (என்னுடைய வேலைகளை என்னால் செய்ய இயலாததால் நிறைய சாந்திருக்கிறேன்)

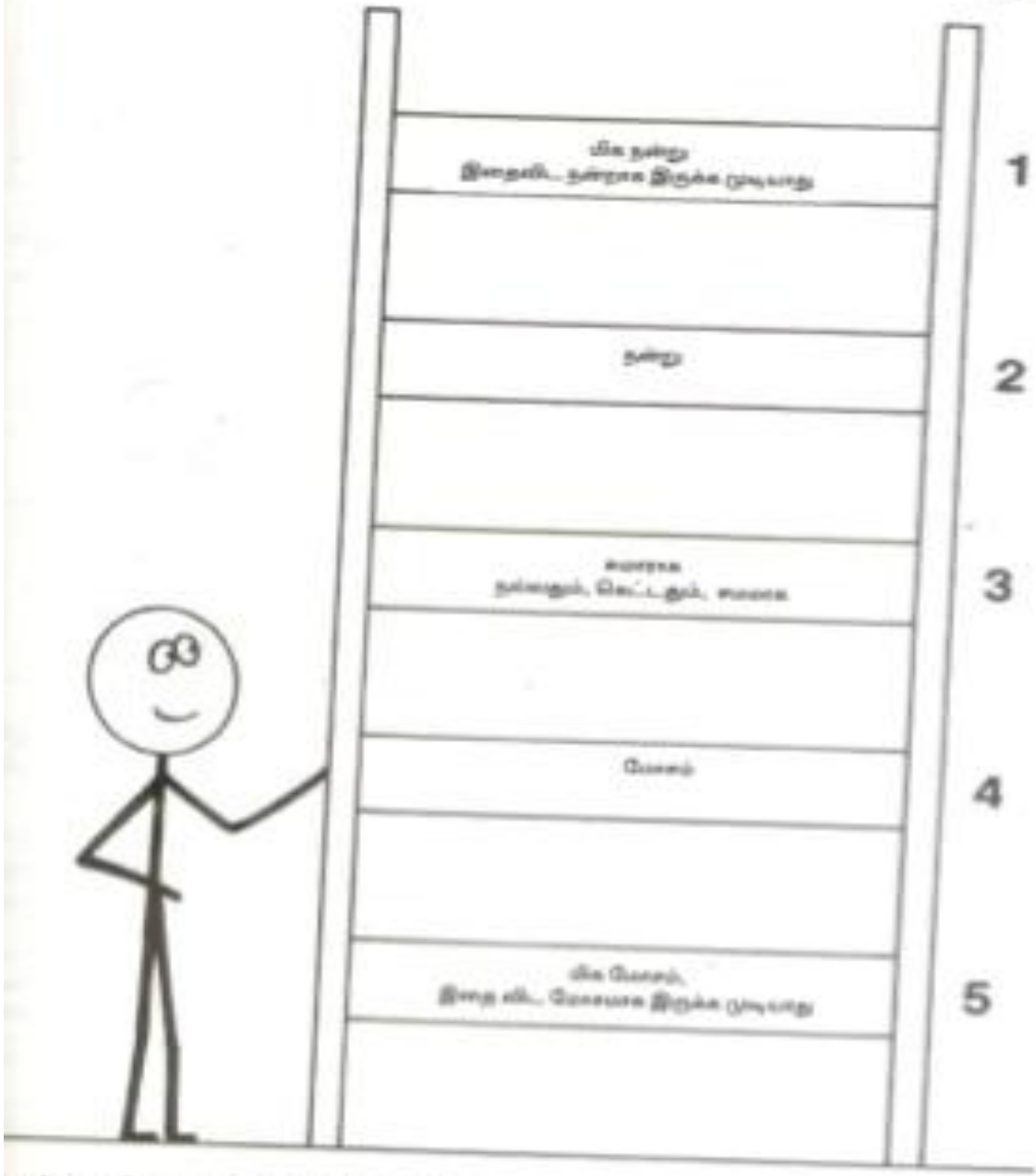
கடந்த 4 வாரங்களில் உங்கள் வாழ்வில் ஏற்பட்ட நிகழ்வுகளை எப்படி உணர்ந்தீர்கள் என்பதை பற்றிய வினாக்கள். தயவு செய்து ஒவ்வொரு வினாவிற்கும் உங்களுக்கு தெரிந்த அளவில் நெருங்கி வரும் விடையை குறிப்பிடவும்

கடந்த 4 வாரங்களில் எத்தனை முறை

வ. எண்		எல்லா நேரமும்	மிக அதிக மன நோய் களில்	அதிக மன நோய் களில்	சில நோய் களில்	ஒரு சில நோய் களில்	எப்போதும் இல்லை
2.	நீங்கள் உற்சாகமாக உணர்ந்தீர்களா?						
3.	நீங்கள் அதிக உணர்ச்சி வசப்படுகிறவரா?						
4.	நீங்கள் மிகவும் சோகமாக உணர்ந்தீர்களா? உங்களை மகிழ்ச்சி அடையவிக்க எதுவும் உதவவில்லையா?						
5.	நீங்கள் அமைதியாகவும் நிம்மதியாகவும் இருப்பதாக உணர்கிறீர்களா?						
6.	உங்களிடம் அதிக பலம் உள்ளதா?						
7.	நீங்கள் உற்சாகமில்லாமலாகவும், மனச்சோர்வாக உணர்ந்தீர்களா?						
8.	நீங்கள் களைப்பாக இருப்பதாக உணர்ந்தீர்களா?						
9.	நீங்கள் சந்தோஷமானவராக இருந்திருக்கிறீர்களா?						
10.	நீங்கள் சோர்வாக உணர்ந்தீர்களா?						
11.	நீங்கள் அடுத்த முறை வகுப்பு வந்துவிடுமோ என்று கவலைப் படுகிறீர்களா?						
12.	உங்களுக்கு யோசித்து பிரச்சனைகளுக்கு தீர்வு காண்பதில் சிரமம் ஏற்பட்டுள்ளதா? (வாழ்வில் திட்டமிடல், முடிவெடுத்தல், புதிய முறைகளை கற்றல் ஆகியன)						
13.	உங்களது உடல்நலம் பொது செயல்பாடுகளில் எடுப்ப... தடையாக உள்ளதா? (தலைவலி / உறவினர்களை சென்று சந்திப்பதில்)						

14. கடந்த 4 வாரங்களில் உங்களது வாழ்க்கை தரம் எந்த நிலையில் இருந்தது.

(Circle one number)



கள்ட.. வினா ஞாபக சக்தி பற்றியது

		மிக அதிகம்	ஆம் ஓரளவு	சிறிதளவு மட்டும்	இல்லை எதுவும் இல்லை
	உங்கள் வாழ்வில் கடந்த 4 வாரங்களில் ஞாபக மறதி தொல்லை இருந்ததா?				

கீழ்கண்ட வினா கடந்த 4 வாரங்களில் நினைவு கொள்வதில் ஏற்பட்ட தொல்லை மற்றும் ஞாபக சக்தி குறைவினால் அன்றாட வாழ்க்கையில் (அல்லது) வேலையில் ஏற்படும் பிரச்சனை பற்றியதாகும்.

வ. எண்		எல்லா நேரமும்	மிக அதிக மான நேரங் களில்	அதிக மான நேரங் களில்	சில நேரங் களில்	ஒரு சில நேரங் களில்	எப்போதும் இல்லை
16.	பிறர் கூறுவதை நினைவில் வைத்து கொள்வதில் சிரமப் படுகிறீர்களா?						

கீழ்கண்ட வினாக்கள், தினைவாற்றலினாலோ, ஞாபக சக்தி பிரச்சனையினாலோ, அன்றாட வாழ்விலோ, செயலிலோ தடங்கள் ஏற்பட்டது பற்றியது.

வ. எண்		எல்லா நேரமும்	மிக அதிக மான நேரங் களில்	அதிக மான நேரங் களில்	சில நேரங் களில்	ஒரு சில நேரங் களில்	எப்போதும் இல்லை
17.	வாசிப்பதில் கவனம் செலுத்த இயலாமை						
18.	வேலை செய்யும் இடத்தில் கொடுக்கப்பட்ட வேலையில் கவனம் செலுத்துவது / வீட்டு வேலைகளில் ஈடுபடல் செய்வது. வீட்டை சுத்தம் செய்வது, குழந்தை வளர்ப்பது ஆகியன						

கீழ்கண்ட வினாக்கள் சில குறிப்பிட்ட வேலைகளைச் செய்யும் போது ஏற்படும் பிரச்சனைகளுக்கானவை:

கடந்த 4 வாரங்களில் வலிப்பு நோயினாலோ / வலிப்பிற்காக எடுத்து கொள்ளும் மருத்துவரினாலோ கீழ்கண்ட வேலைகளைச் செய்யும் போது எந்த அளவிற்கு பிரச்சனைகளை ஏற்படுத்தியது.

வ. எண்		மிக அதிகம்	அதிகம்	முறையு	சிறிதளவு மட்டும்	ஒரு போதும் இல்லை
19.	பொழுதுபோக்கில் இடையூறு (வெளியே செல்வது)					
20.	பயணம் செய்வதில் இடையூறு					

கீழ்கண்ட கேள்விகள் வலிப்பைப் பற்றி நீங்கள் என்ன எண்ணுகிறீர்கள் என்பதை பற்றியதாகும்.

வ. எண்		மிகவும் பயமாக உள்ளது	ஏதோ ஒரு பய உணர்வு	ரொம்ப பயமில்லை	பயமே இல்லை
21.	அடுத்த முறை வலிப்பு வருமோ என்ற பய உணர்வு எவ்வாறுள்ளது?				

வ. எண்		அதிக கவலை	எப்பொழுதாவது கவலை	எப்பொழுதும் கவலைப் பட்டதில்லை
22.	வலிப்பு வரும்போது அடிபட்டுவிடுமோ என்ற கவலை உள்ளதா?			

வ. எண்		மிகவும் கவலைப் படுகிறேன்	கொஞ்சம் கவலைப் படுகிறேன்	ரொம்ப கவலைப் படுகிறேன்	கவலை ஏதுமில்லை
23.	அடுத்தபடி வலிப்பு ஏற்பட்டால் மற்றவர்கள் என்ன நினைப்பார்கள் என்பது பற்றியும் அதனால் ஏற்படும் சமூகப் பிரச்சனை பற்றியும் எந்த அளவுக்குக் கவலைப்படுகிறீர்கள்.				

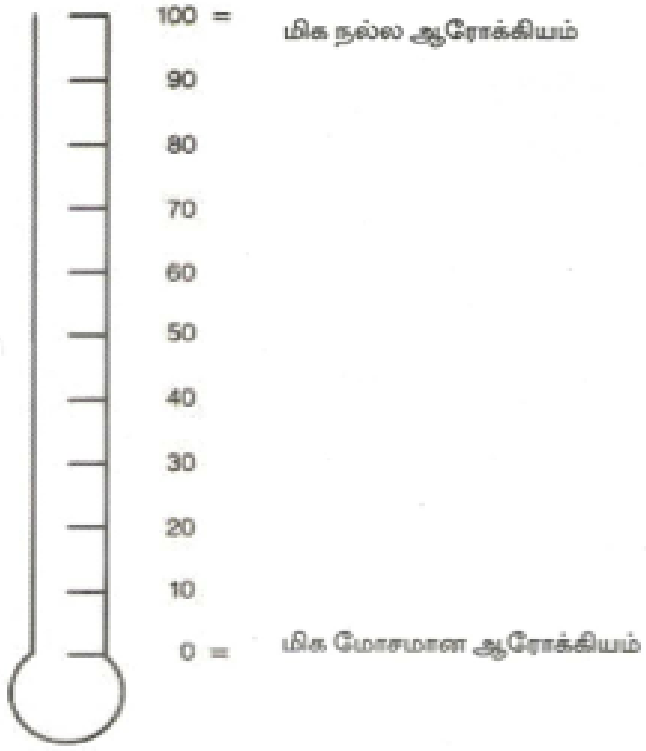
வ. எண்		மிகவும் கவலைப் படுகிறேன்	கொஞ்சம் கவலைப் படுகிறேன்	ரொம்ப கவலைப் படுகிறேன்	கவலை ஏதுமில்லை
24.	நீண்ட காலமாக நீங்கள் எடுத்துக் கொள்ளும் மருத்தினால், உங்களுக்கு ஏதாவது பாதிப்பு ஏற்படும் என்று எவ்வளவு கவலைப்படுகிறீர்கள்?				

ஒவ்வொரு பிரச்சனையும் உங்களை எந்த அளவுக்கு பாதிக்கிறது என்பதைக் குறிப்பிடுக.
(1) பாதிப்பு ஏதுமில்லை (5) அதிகமான பாதிப்பு

		1	2	3	4	5
25.	வலிப்பு					
26.	ஞாபக சக்தி கடினம்					
27.	வேலை செய்யும் அளவு					
28.	சமூக உறவின் அளவு					
29.	மாத்திரைகளால் ஏற்படும் உடல் நலக்குறைவு					
30.	மாத்திரைகளால் ஏற்படும் மனநலக் குறைவு					

1. எந்த அளவு நல்லதாகவோ, மோசமாகவோ உங்கள் ஆரோக்கியத்தை உணர்கிறீர்கள்?

1-100க்குள் உள்ள அளவு கோலில் குறிப்பிடுக. உங்கள் வலிப்பு நோயை உங்கள் ஆரோக்கியத்தின் ஒரு பகுதியாகக் கருதிக் கொண்டு பதில் அளிக்கவும்



றிப்பு (ஏதேனும்)

ANNEXURE 5:- IRB APPROVAL LETTER

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Alfred Job Daniel, D Ortho MS Ortho DNB Ortho.
Chairperson, Research Committee & Principal

Dr. Nihal Thomas,
MD, MNAMS, DNB (Endo), FRACP (Endo), FRCP (Edin), FRCP (Glasg)
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

November 30, 2015

Dr. [redacted]
PG Registrar
Department of Community Medicine,
Christian Medical College,
Vellore 632 004.

Sub: **Fluid Research Grant NEW PROPOSAL:**
Assessment of the Health related quality of life among adults with Epilepsy living in Kaniyambadi Block of Vellore District and factors associated with poor quality of life among them.
Dr. [redacted] PG Registrar, Community Medicine, Dr. Venkata Raghava (Emp. No. 20303), Community Medicine, Dr. Jasmin Helan, Community Health

Ref: IRB Min No: 9609 [OBSERVE] dated 01.09.2015

Dear Dr. [redacted]
The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Assessment of the Health related quality of life among adults with Epilepsy living in Kaniyambadi Block of Vellore District and factors associated with poor quality of life among them" on September 01st 2015.

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Nihal Thomas, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

Dr. NIHAL THOMAS
MD.,MNAMS.,DNB(Endo),FRACP(Endo),FRCP(Edin),FRCP(Glasg)
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc: Dr. Venkata Raghava, Dept. of Community Medicine, CMC

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

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November 30, 2015

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Ref: IRB Min No: 9609 [OBSERVE] dated 01.09.2015

Dear Dr. [redacted]
The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Assessment of the Health related quality of life among adults with Epilepsy living in Kaniyambadi Block of Vellore District and factors associated with poor quality of life among them" on September 01st 2015.

The Committee raised the following documents

1. IRB Application format
2. Questionnaire (English and Tamil)
3. Information Sheet and Consent Form (English, Tamil)
4. Quality OF Life In Epilepsy (English, Tamil)
5. Cvs of Drs. [redacted] and Venkata Raghava
6. No. of documents 1- 5

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on September 01st 2015 in theCREST/SACNConferenceRoom,Christian Medical College, Bagayam, Vellore 632002.

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
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Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Name	Qualification	Designation	Affiliation
Dr. B. J. Prashantham	MA(Counseling Psychology), MA(Theology), Dr. Min(Clinical Counselling)	Chairperson, Ethics Committee, IRB. Director, Christian Counseling Centre, Vellore	External, Social Scientist
Dr. Nihal Thomas	MD, MNAMS, DNB(Endo), FRACP (Endo) FRCP(Edin) FRCP (Glasg)	Professor & Head, Endocrinology. Additional Vice Principal (Research), Deputy Chairperson (Research Committee), Member Secretary (Ethics Committee), IRB, CMC, Vellore	Internal, Clinician
Mrs. Pattabiraman	BSc, DSSA	Social Worker, Vellore	External, Lay Person
Rev. Joseph Devaraj	BSc, BD	Chaplaincy Department, CMC, Vellore	Internal, Social Scientist
Dr. Jayaprakash Muliyil	BSc, MBBS, MD, MPH, Dr PH (Epid), DMHC	Retired Professor, CMC, Vellore	External, Scientist &Epidemiologist
Mrs. Emily Daniel	MSc Nursing	Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse
Mrs. Sheela Durai	MSc Nursing	Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse
Mr. C. Sampath	BSc, BL	Advocate, Vellore	External, Legal Expert
Dr. Anuradha Rose	MBBS, MD, MHSC (Bioethics)	Associate Professor, Community Health, CMC, Vellore	Internal, Clinician
Dr. Denise H. Fleming	BSc (Hons), PhD	Honorary Professor, Clinical Pharmacology, CMC, Vellore	Internal, Scientist & Pharmacologist
Dr. Chandrasingh	MS, MCH, DMB	Professor, Urology, CMC, Vellore	Internal, Clinician

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Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Dr. Visalakshi. J	MPH, PhD	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician
Dr. Simon Pavamani	MBBS, MD	Professor, Radiotherapy, CMC, Vellore	Internal, Clinician
Dr. Inian Samarasam	MS, FRCS, FRACS	Professor, Surgery, CMC, Vellore	Internal, Clinician
Dr. Balamugesh	MBBS, MD(Int Med), DM, FCCP (USA)	Professor, Pulmonary Medicine, CMC, Vellore	Internal, Clinician
Dr. Niranjan Thomas	DCH, MD, DNB (Paediatrics)	Professor, Neonatology, CMC, Vellore	Internal, Clinician
Dr. Mathew Joseph	MBBS, MCH	Professor, Neurosurgery, CMC, Vellore	Internal, Clinician

We approve the project to be conducted as presented.

Kindly provide the total number of patients enrolled in your study and the total number of withdrawals for the study entitled: "Assessment of the Health related quality of life among adults with Epilepsy living in Kaniyambadi Block of Vellore District and factors associated with poor quality of life among them" on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in)

Fluid Grant Allocation:

A sum of 17,300/- INR (Seventeen Thousand Three Hundred Only) will be granted for 12Months and out of which a maximum of Rs.5000/- can be spent for stationery, printing, Xeroxing and computer charges(if computers used are within the institution)

Yours sincerely

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

Dr. NIHAL THOMAS
MD,MNAMS,DNB(Endo),FRACP(Endo),FRCP(Edin),FRCP(Glasg)
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

IRB Min No: 9609 [OBSERVE] dated 01.09.2015

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